

Summing Up

The Ethical and Legal
Problems in Medicine
and Biomedical and
Behavioral Research



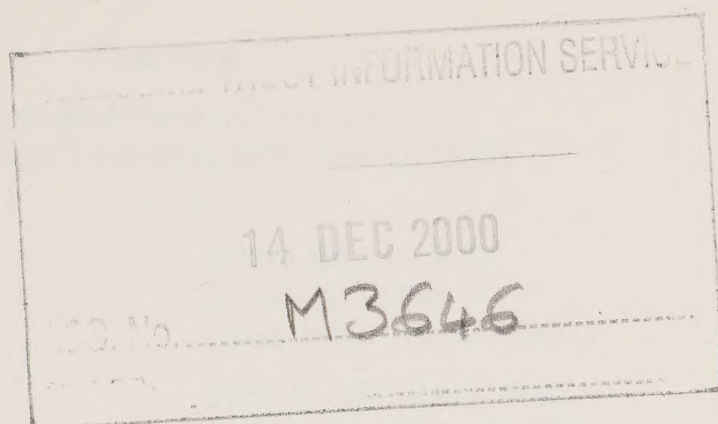
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Commission for the Study of
Problems in Medicine and
Biomedical and Behavioral Research



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Summing Up



Final Report on Studies of the Ethical and Legal Problems in Medicine and Biomedical and Behavioral Research

March 1983

President's Commission for the Study of
Ethical Problems in Medicine and
Biomedical and Behavioral Research

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President's Commission for the Study of Ethical Problems
in Medicine and Biomedical and Behavioral Research

Suite 555, 2000 K Street, N.W., Washington, DC 20006 (202) 653-8051

March 31, 1983

The President
The White House
Washington, D.C. 20500

Dear Mr. President:

I am pleased to transmit the Final Report of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. As you know, the Commission's statutory authority expires today. This volume provides an overview of the Commission's work since our inception in January 1980. During the past three years, we have published eleven volumes--nine reports, the proceedings of a workshop on whistle-blowing in research, and a guidebook for the local committees that review research with human beings.

The basic American values of liberty, fairness, compassion, and respect for human dignity have recurred in many settings throughout our work. In light of these values, we have addressed many of the most troubling issues facing Americans in the last quarter of this century, such as: When, if ever, should life-sustaining treatment be foregone? Who should bear the costs of injuries to human subjects in research? Should society ensure that everyone gets health care and, if so, how much? Ought physicians to tell their patients the truth, even if it is very dismal? What should be done about attempts to remake human genes?

In this Report, Summing Up our work, we review each of our projects and the current status of the recommendations we have made. I am happy to say that our studies have provoked a great deal of interest, and we hope that even after our closing these reports will go on stimulating thoughtful discussion of the important issues of bioethics not only in Washington but also among people across the country. Some of our conclusions are broadly applicable to health professionals and patients, while others involve governmental action. We trust that recommendations of the latter sort will continue to receive prompt and careful attention from yourself and others in the Administration.

We are truly grateful for the opportunity to have served on this Commission and hope that we contributed to public understanding and the development of sound policy on these vital issues.

Respectfully,

A handwritten signature in dark ink, appearing to read "Morris B. Abram". The signature is fluid and cursive, with a long horizontal stroke at the end.

Morris B. Abram
Chairman

Copies to: Honorable George Bush
Honorable Thomas P. O'Neill, Jr.

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Scope of Activities

1

Who will live and who will die? Who decides, and on what grounds? Are there certain characteristics—when “defining” life or setting the boundaries of permissible genetic experimentation—that are essential for “humanness”? In distributing risks and benefits, when should choices be left to the consciences of individuals and when should they be constrained collectively—by expert or lay groups, legislators, administrators, or judges?

The awesome powers of medicine, which are continually expanded by developments in the life sciences, have sparked growing public interest in a number of what are now termed “bioethical” issues. To the traditional matters of personal conscience for physicians and other health care professionals have been added the increasingly difficult questions that face courts, legislators, sponsors and regulators of research, and patients and their families as biomedical and behavioral scientists and practitioners explore new ways to conquer illness, to sustain organ functions artificially, to probe and even manipulate the genetic basis of life itself.

Although public awareness of bioethics has been galvanized by the dramatic achievements that emerge from hospitals and research laboratories—and occasionally by reports of research abuses—the concerns are not just momentary ones, nor are they necessarily best addressed in the context of particular revelations or discoveries, however startling. For these reasons, the U.S. Congress in November 1978 authorized the creation of a presidential commission with continuing responsibility to study and report on the ethical and legal implications of a number of issues in medicine and research,

and gave the Commission the power to extend that list as it or the President saw fit.¹ It was intended that the Commission would have approximately four years from its statute until its legislative “sunset.” Delays in appointing and funding the Commission meant that it has had to complete all its assigned studies—and several additional ones—in a little more than three years. The mandate of the Commission expanded on the work of earlier Federal bodies that had primarily dealt with ethical issues in research with human beings.² This mandate reflects the Congressional conclusion that, just as medical and scientific activities merit public support, the wide range of bioethical issues raised by these activities deserve to be considered in a public forum.

Commissions are established for a number of reasons. Sometimes the intent is “merely to allow deferral of action on a problem that confronts a legislative or governmental agency.”³ Although this may have played a part in the creation of the President’s Commission’s predecessor, the National Commission for the Protection of Human Subjects, in 1974—and especially in the National Commission’s mandate to study such highly charged subjects as fetal research and psychosurgery⁴—similar controversy did not surround the instructions given the President’s Commission. Nor was the Commission empaneled to offer advice on a highly technical matter or on subjects involving primarily the operation or policies of the Federal government.

¹ Title III of Public Law 95-622, enacted on Nov. 9, 1978, and codified at 42 U.S.C. Ch.6A, authorized the creation of the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research with a “sunset” date of Dec. 31, 1982, subsequently amended to March 31, 1983 by Public Law 97-377 (Dec. 20, 1982).

² Title III of the National Research Act of 1974, P.L. 93-348, created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. That body, which was appointed by the Secretary of Health, Education, and Welfare, studied primarily issues in human research; between 1975 and 1978 it issued a series of reports that became the basis for a revision of the HHS regulations governing the protection of research subjects. One of the Commission’s recommendations that was adopted by the Department was the creation of an Ethics Advisory Board to review proposals for research on particularly vulnerable subjects. An EAB was appointed by Secretary Califano in 1978; it was dissolved by Secretary Harris in 1980 after the establishment of the President’s Commission, although HHS regulations continue to provide for the existence of such a board. See, e.g., 45 CFR 46.204.

³ Michael S. Yesley, *The Use of an Advisory Commission*, 51 S. CAL. L. REV. 1451, 1452 (1978). This seems to have been the effect of the Ethics Advisory Board of the Department of Health, Education, and Welfare in its 1978-79 study of research involving human *in vitro* fertilization.

⁴ National Research Act, Pub. L. No. 93-348, § 202, 88 Stat. 342 (1974).

Instead, the Commission was charged with studying problems whose value components are at least as important as their technical aspects. In effect, the Commission was instructed to bring ethical analysis of the implications of medical practice and research out of the classrooms, the hospital wards, and the scholarly journals and into a public forum in Washington. If not unique in the annals of government panels, the President's Commission was at least highly unusual. In fulfilling its mandate, the Commission has chosen to speak to many different audiences, depending upon the topic—not only the President and Congress, to whom it reports directly, but also the American people, as individuals and as members of professional associations, law reform bodies, groups of state and local officials, and religious and civic organizations.

The topics scrutinized by the President's Commission over the past three years have carried it to the heartlands as well as the frontiers of biomedical practice and investigation. The enormously challenging issues addressed by the Commission are not arcane. Rather, they are questions that increasingly confront all Americans, individually as participants in health care and collectively as citizens in a democracy in which many bodies, from local hospitals to Federal agencies, must grapple with issues of life and death. The intention of the Commission in all its reports has been

- to help clarify the issues and highlight the facts that appear to be most relevant for informed decisionmaking;
- to suggest improvements in public policy at various levels, not exclusively Federal, and through various means, not—it turned out—primarily legislative; and
- to offer guidance for people involved in making decisions, though not to dictate particular choices on moral grounds.

Since mid-1981 the Commission has published most of its findings and conclusions in a series of nine reports.⁵ The

⁵ These reports are described more fully in Chapters Two and Three *infra*. In each case, the Commission's report was in a single volume; for some subjects, supporting materials and documents are included in the same publication, while for others one or more appendix volumes were published. In addition, the Commission submitted Annual Reports for fiscal years 1980, 1981, and 1982 to the President and Congress in December of each year, as required by Public Law 95-622.

The Commission also published a guidebook (in a looseleaf binder) for participants in the process by which studies with human subjects are reviewed at research institutions and the proceedings of a Sept. 1981 workshop on whistleblowing in biomedical research, which was held at the National Academy of Sciences under joint sponsorship. These projects are summarized in Chapter Three *infra*.

purposes of this final report are to summarize the Commission's work, to place the individual studies into a larger context, and to look to the future, in terms both of the issues studied by the Commission on which responses are pending and of the need for further attention to the impact of bioethics on matters of importance to the public. This volume also contains a summary of the Commission's work and conclusions on its Congressionally mandated study of privacy and confidentiality in medicine, which have not been previously presented in a separate report.

Membership

On July 18, 1979, President Carter announced his intention to name 11 Commissioners, and on September 29, 1979, the Senate gave its advice and consent to the appointment of Morris B. Abram as Chairman. The enabling legislation mandated that:

- (1) three of the members shall be appointed from individuals who are distinguished in biomedical or behavioral research;
- (2) three of the members shall be appointed from individuals who are distinguished in the practice of medicine or otherwise distinguished in the provision of health care; and
- (3) five of the members shall be appointed from individuals who are distinguished in one or more of the fields of ethics, theology, law, the natural sciences (other than a biomedical or behavioral science), the social sciences, the humanities, health administration, government, and public affairs.⁶

The Commission officially began its work on January 14, 1980, when the original members were sworn in at the White House by Judge David L. Bazelon. The three Commissioners representing biomedical or behavioral research were Mathilde Krim, an associate member of the Sloan-Kettering Institute for Cancer Research and coordinator of its International Laboratories for the Molecular Biology of Interferon Systems; Arno G. Motulsky, a professor of medicine and genetics and Director of the Center for Inherited Diseases at the University of Washington; and Frederick C. Redlich, a professor of psychiatry at UCLA Medical School and former Yale Medical School Dean.

The three Commissioners distinguished in the practice of medicine were Mario García-Palmieri, a professor and Head of the Department of Medicine at the University of Puerto Rico and former Secretary of Health for the Commonwealth; Donald N. Medearis, Chief of the Children's Service at Massachusetts

⁶ 42 U.S.C. § 300v(a)(1).

General Hospital and Charles Wilder Professor of Pediatrics at Harvard University; and Charles J. Walker, a physician in private practice in Nashville, Tennessee, and a member of the Board of Trustees at Fisk University.

The five Commissioners from the fields other than medical research and practice were Morris B. Abram (Chairman), a New York City attorney, formerly President of Brandeis University and U.S. Representative to the United Nations Commission on Human Rights; Renée C. Fox, a leading medical sociologist and Annenberg Professor of the Social Sciences at the University of Pennsylvania; Albert R. Jonsen, Chairman of the Bioethics Group for the five University of California schools of medicine and member of the former National Commission for the Protection of Human Subjects; Patricia A. King, an associate professor of law at Georgetown University and also a member of the former National Commission for the Protection of Human Subjects; and Anne A. Scitovsky, Chief of the Health Economics Division of the Palo Alto Medical Research Foundation.⁷ (For further biographical information on all the Commissioners, see Appendix A.)

In February 1980 Dr. Redlich resigned as a member of the Commission because, in addition to his position at UCLA, he was Acting Director of the Veterans Administration Hospital in Brentwood, California, and the authorizing legislation precluded the appointment of full-time employees of the Federal government to the Commission. Frances K. Graham, Hilldale Professor of Psychology and Pediatrics at the University of Wisconsin and former President of the Society for Research in Child Development, was sworn in to replace Dr. Redlich on May 16, 1980. Commissioner King resigned in May 1980 to accept a position with the Department of Justice. Carolyn A.

⁷ In addition, P.L. 95-622 directed the heads of six Federal agencies to provide the Commission with liaison officers. Liaison has been provided as follows: Department of Health and Human Services—Charles R. McCarthy, Ph.D., Director, Office for Protection from Research Risks, Office of the Director, NIH, assisted by Richard Riseberg, HHS, Office of General Counsel, and Stuart Nightingale, M.D., Associate Commissioner for Health Affairs, FDA; Department of Defense—Captain Peter A. Flynn, MC, USN, Special Assistant for Professional Activities, Office of the Assistant Secretary of Defense (Health Affairs); Central Intelligence Agency—Bernard M. Malloy, M.D., Chief of the Psychiatric Division, Office of Medical Services, assisted by Dennis Foreman, Office of General Counsel; Office of Science and Technology Policy—Gilbert S. Ommen, M.D., Ph.D., Associate Director for Human Resources and Social and Economic Services, OSTP, Executive Office of the President, succeeded by John Ball, M.D., J.D., succeeded by Denis Prager, Ph.D.; Veterans Administration—Dorothy C. Rasinski, M.D., J.D., Associate Director, Medical Legal Affairs; National Science Foundation—Richard T. Louttit, Ph.D., Division Director for Behavioral and Neural Sciences.

Williams, a faculty member in epidemiology and nursing at the University of North Carolina at Chapel Hill, was sworn in as her successor on September 16, 1980.

Four new Commissioners were announced by President Reagan on January 25, 1982, to replace Commissioners Graham, Medearis, and Fox, whose two-year terms had ended, and Commissioner Krim, who resigned in October 1981 due to conflicting commitments (Appendix B). The new Commissioners were George R. Dunlop, a professor of surgery at the University of Massachusetts Medical School and former President of the American College of Surgeons; Daher B. Rahi, a physician in private practice in St. Clair Shores, Michigan, and former President of the Michigan Association of Osteopathic Physicians and Surgeons; Seymour Siegel, a professor of ethics and theology at the Jewish Theological Seminary of America and professor of humanities in medicine at the Medical College of Pennsylvania; and Lynda Hare Smith, a Colorado Springs housewife and advisor to the Chancellor of the University of Colorado Health Science Center. Drs. Dunlop and Rahi and Rabbi Siegel were sworn in at the Commission's meeting on February 1982, and Mrs. Smith joined the Commission the following month.

President Reagan nominated four additional Commissioners on July 12, 1982, to succeed Commissioners García-Palmieri, Jonsen, Scitovsky, and Williams, whose terms of office were ending that month. The new Commissioners, sworn in at the Commission's meeting on August 12, 1982, were H. Thomas Ballantine, Jr., a clinical professor of neurological surgery at Harvard Medical School and Senior Neurosurgeon at Massachusetts General Hospital; Bruce Kelton Jacobson, Director of the Family Practice Residency Program at John Peter Smith Hospital in Fort Worth, Texas, and an associate professor of family practice and community medicine at Southwestern Medical School; John J. Moran, Director of the Moran Foundation in Houston, Texas, and former owner of a company that makes diagnostic reagents and instruments for the professional medical community; and Kay Toma, a physician in private practice in Bell, California, and President of the Bell Medical Center.

Staff and Funding

The Commission's work was directed by Alexander Morgan Capron, who was on leave from the University of Pennsylvania, where he was a professor of law and of human genetics; at the conclusion of the Commission's work, Mr. Capron joined the faculty of Georgetown University as a professor of law, ethics, and public policy. The Deputy Director was Barbara Mishkin, former Assistant Director of the National Commission for the Protection of Human Subjects and Staff

Director of the HEW Ethics Advisory Board. Mrs. Mishkin's primary responsibility was for the Commission's work in the area of biomedical and behavioral research.

Joanne Lynn, a former director of clinical services in the Division of Geriatric Medicine at George Washington University, served as Assistant Director for Medical Studies. Dr. Lynn directed the Commission's study on decisionmaking about life-sustaining treatment; she also participated in the study of informed consent and in the medical aspects of other projects. The position of Assistant Director of Legal Studies was filled first by Alan Weisbard, formerly a practicing attorney in the field of administrative law, and then by Alan Meisel, a professor of law, psychiatry, and sociology at the University of Pittsburgh. Mr. Weisbard worked primarily on informed consent, as well on the studies of compensation for research injuries and decisions about life-sustaining treatment. When Mr. Weisbard left to join the faculty of Cardozo School of Law, Professor Meisel took over direction of the legal studies on informed consent and decisions to forego life-sustaining treatment.

The position of Staff Ethicist, which entailed collaboration on all the studies related to health care, was filled in succession by three professors of moral philosophy: Daniel Wikler, of the University of Wisconsin; Dan Brock, chairman of the department at Brown University; and Allen Buchanan, of the University of Minnesota and the University of Arizona.

Renie Schapiro, a former staff fellow in the Office of the Commissioner at the Food and Drug Administration, provided expertise in the area of public health. Ms. Schapiro worked primarily in the areas of genetic screening and counseling, genetic engineering, and decisionmaking about the care of seriously ill newborns; she also provided assistance in epidemiology for the study on defining death.

The Commission's work on access to health care was directed by Susan Morgan, who was formerly Director of the Division of Health Resources and Services Analysis in the Department of Health and Human Services. She was assisted by the staff economist, Mary Ann Baily, formerly an assistant professor of economics at Yale University, and by Kathryn Kelly, whose training is in public health and social welfare.

Marian Osterweis, on leave from the Departments of Community and Family Medicine and of Sociology at Georgetown University, served as the Commission's staff sociologist. Professor Osterweis worked primarily on the studies of informed consent and decisions to forego life-sustaining treatment; she also assisted the empirical studies regarding compensation for research injuries.

In addition to the full-time professional staff, Bradford Gray, a senior staff member at the Institute of Medicine and

former staff sociologist for the National Commission for the Protection of Human Subjects, served as a special consultant to the President's Commission. Dr Gray directed a pilot study on the value of site visits to Institutional Review Boards.

The Commission's Public Information Officer was Andrew Burness, formerly an assistant for health and education policy to Representative Richardson Preyer of North Carolina. The Commission's permanent staff positions also included an administrative officer, a staff assistant responsible for meeting management, and a secretary. In addition, the Commission's temporary positions included two research assistants, two secretaries, a staff aide, two editors, and a philosophy graduate student who served as a part-time consultant to assist the Deputy Director on the research-related reports.

The Commission laundered an internship program for the summer of 1980 in order to introduce students in philosophy, medicine, law, and related fields to the practical implications of bioethics. To broaden the basis of this program to include term-time appointments, as well as to relieve the strain on the Commission's budget created by the program, the Commonwealth Fund created a fellowship program that provided \$25,000 for the period from May 1981 to September 1982. Under this program, which was administered by the Institute of Society, Ethics and the Life Sciences (The Hastings Center), applicants were sought through direct contact with numerous graduate and professional schools and through an announcement in the *Hastings Center Report*. Approximately 60 students applied each year. Overall 14 graduate students assisted the professional staff during the course of the Commission's work. They included law students, medical students, and graduate students in health policy, genetic counseling, psychology, and philosophy. Each summer, the Commission also had the voluntary services of an undergraduate intern.

Although authorized at \$20 million (\$5 million per year for four years), the Commission expended less than \$4 million over its lifetime. The Commission's funding for the nine months of fiscal year 1980 took the form, with the consent of Congress, of reprogrammed funds from the Department of Health and Human Services (then HEW) in the amount of \$697,500. (The amount originally provided was \$1,200,000; \$502,500 was returned to HHS because, in the Commission's judgment, the full amount could not be expended wisely in fiscal year 1980, especially since the projects that the Commission undertook during its first months did not involve large empirical surveys.) For fiscal year 1981, 1981, President Carter requested an appropriation of \$2,054,000, and the Commission actually operated with a budget authority of \$1,545,000 under the series of continuing resolutions that funded agencies in the health area of the Federal budget. For fiscal year 1982, President

Reagan initially requested an appropriation of \$2,200,000 for the 15 months through December 31, 1982. The Senate Appropriations committee approved \$2,000,000 and the House voted \$1,500,000; the latter amount, decreased by the government-wide 4% reduction under the September 1981 Continuing Resolution, provided initial funding of \$1,440,000. This was increased to \$1,749,000 by the July 1982 Urgent Supplemental Appropriations Act; these funds supported the Commission for the 18 months through its closing on March 31, 1983, under the terms of the December 1982 Continuing Resolution.

Procedures

Commission Meetings. The Commission held 28 meetings between January 1980 and March 1983. Typically, two-day meetings were held once a month. All meetings were open to the public, and attendance ranged from 25 to 200 persons. Twenty-four meetings were held in or near Washington, D.C.⁸ In order to gather information and to make the Commission more accessible nationally, four meetings were held in other parts of the country: in Boston, Atlanta, Miami, and Los Angeles. Notice of each meeting and of the topics to be discussed was published in the *Federal Register* and announced in the minutes that were distributed to approximately 1500 individuals and organizations on the Commission's mailing list.

Information Gathering. Prior to each meeting, the Commissioners were provided with briefing books that contained extensive background materials taken from the existing literature as well as new studies prepared by staff, contractors, and consultants to the Commission. The Commission contracted for scholarly studies in all areas of its mandate. These included large empirical studies, small pilot projects, and analytical research papers. Studies conducted under contract are published in the appendices of the relevant reports.

The Commission heard testimony from more than 300 scheduled witnesses including philosophers, physicians, biologists, lawyers, clergy, political and social scientists, university and hospital administrators, members of the insurance industry, representatives of the Federal government, representatives of interest groups (such as the Association of American Medical Colleges, the American Psychological Association, and the American Council on Education), and members of the public, including health care consumers. In each area of inquiry, special care was taken to solicit the views of

⁸ The Commission is especially grateful to the U.S. Water Resources Council and to the Medical Society of the District of Columbia for allowing their meeting rooms to be used by the Commission for public hearings on numerous occasions.

individuals with firsthand experience in the area under study and to obtain a balanced range of viewpoints. And at each meeting, time was set aside for comments from the floor by members of the general public.

In addition to testimony at Commission meetings, advice was sought from several panels convened by the Commission staff. For example, nurses drawn from practice, academia, and government addressed the topics in the Commission's mandate, particularly the areas of informed consent and decisions to forego life-sustaining treatment; a group of philosophers considered the issue of distributive justice in the availability of health care; neurologists, neurosurgeons, anesthesiologists, pediatricians, and other medical experts prepared clinical guidelines for the determination of death; and biologists, physicians, lawyers, philosophers, and social scientists assisted in identifying the ethical, social, and legal issues in the use of gene splicing in human beings. Other panels were convened to discuss access to health care, protection of human subjects, compensation of injured research subjects, the definition of death, and informed consent. (For a complete list of witnesses and panel members, see Appendix C.)

Dissemination of Information. In order to keep the public informed of its activities, the Commission developed an extensive information program. Each meeting of the Commission was covered by both local and national print and broadcast media. Commission representatives appeared on national network news and public information programs, on cable and public broadcasting programs, and on television programs in cities where the Commission met. Radio coverage was also local, national, and international in scope. The Commission also learned more about public opinion when talk show hosts invited its representatives to appear on programs originating in virtually every part of the country. The Commission's work received particular attention in journals addressed to specialists in the fields covered by Commission studies. Commission representatives also met with academic, civic, and public interest groups, both in and outside of Washington. The staff testified before Congress on fraud in research, implementation of regulations for the protection of human subjects, genetic screening, and genetic engineering.

As a follow-up to each meeting, detailed minutes were distributed to a mailing list of approximately 1500 individuals and organizations, including members of the lay public, Congressional and Federal agency staff, scientific and professional organizations, public interest groups, the media, and university professors and researchers. An informational brochure about the Commission was also circulated. Additionally, all materials provided to the Commissioners were available to the public upon request. In order to provide a permanent

record of its activities that will be readily accessible to scholars, the Commission provided complete sets of meeting notebooks to the libraries of the Institute of Society, Ethics and the Life Sciences in Hastings-on-Hudson, New York, and the Kennedy Institute of Bioethics at Georgetown University, in Washington, D.C.

In addition to being sent to people on the Commission's mailing list, copies of the nine Commission reports are placed in the Federal regional depository libraries by the Superintendent of Documents. The format for the reports are designed by Peter Masters, Director of General Service Administration's Graphic Communications and Design Staff. The graphic design and illustrations were executed by Sharon Waltersdorff, of GSA, and by Linda Berns and Lee Schuyler of Berns & Kay, in conjunction with the Commission's staff.

The Commission prepared five reports on topics related to the provision of health care: *Defining Death* (July 1981); *Making Health Care Decisions* (October 1982); *Screening and Counseling for Genetic Conditions* (February 1983); *Securing Access to Health Care* (March 1983); and *Deciding to Forego Life-Sustaining Treatment* (March 1983). The first four topics were assigned to the Commission by the Congress; the fifth was added early in the Commission's tenure when it arose during the study on the "definition" of death and because it applied several areas of the Commission's work to a set of ethical problems of great importance and immediacy. In addition, as part of its statutory mandate, the Commission studied the ethical aspects of privacy and confidentiality in the health field; for several reasons, it chose not to issue a separate report on that subject but to present its conclusions in this final report.

The Definition of Death

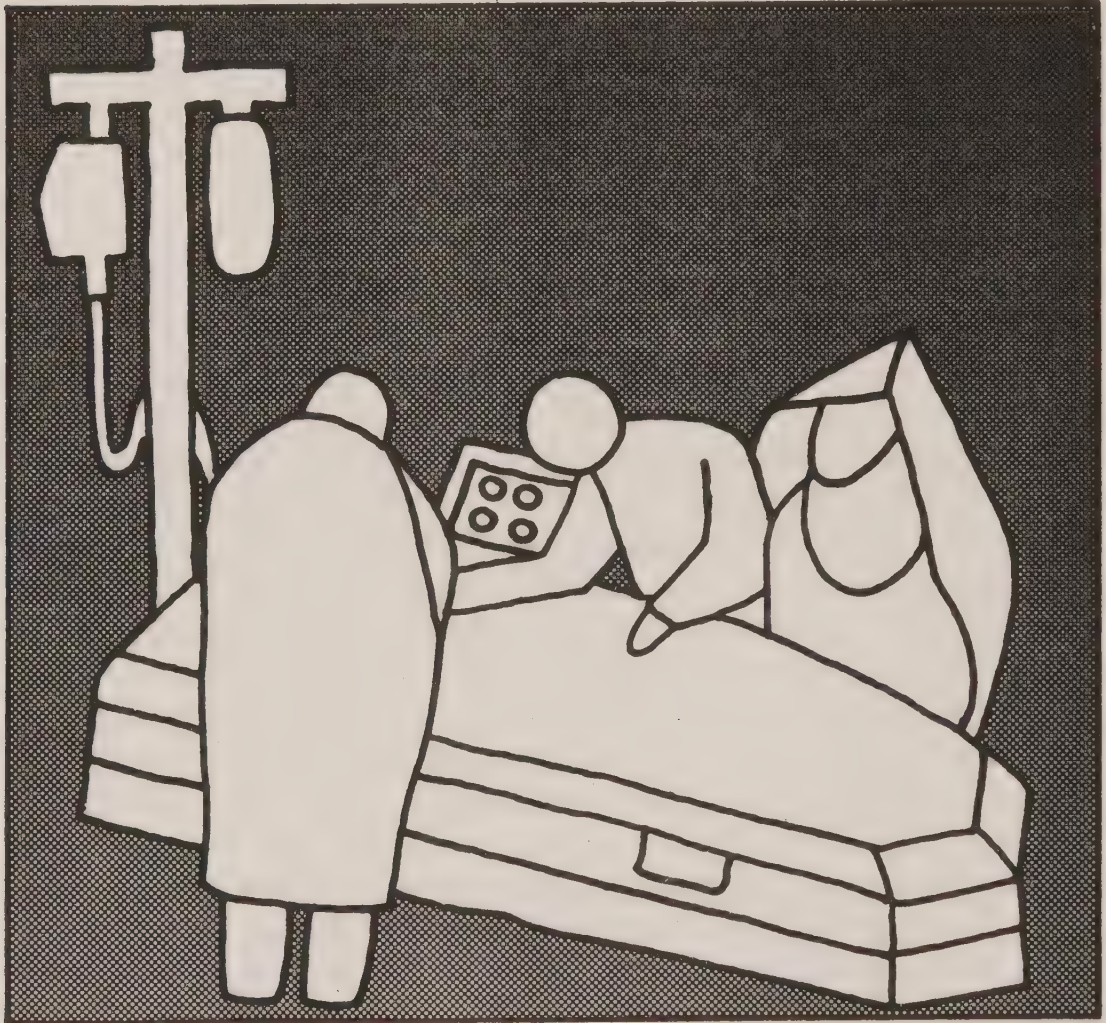
Death is the one great certainty. The subject of powerful social and religious rituals and moving literature, it is contemplated by philosophers, probed by biologists, and combatted by physicians. Death, taboo in some cultures, preoccupies others....The question addressed here is not inherently difficult or complicated. Simply, it is whether the law ought to recognize new means for establishing that the death of a human being has occurred.

Defining Death, p. 3

The Issues. The first issue posed in the Commission's mandate is whether the law ought to recognize new means for establishing that human death has occurred. Although straight-

forward, this question has seemed troublesome for several reasons.

In a small number of cases, ventilators and associated medical technologies can maintain heartbeat and respiration in dead bodies—those having sustained total and irreversible cessation of all brain functions. Thus, the beating heart has sometimes lost the importance customarily accorded it in differentiating the living from the dead.



Moreover, confusion arises because the same technology that keeps heart and lungs functioning—and that thus masks the meaning of these functions in some dead people—can also sustain life in others who have been less severely injured. Inexact medical and legal descriptions of these two categories of cases have blurred of the important distinction between patients who are *dead* and those who are *dying*, though perhaps beyond any reasonable probability of recovery. The latter situation is more problematic in medical, ethical, and legal terms and became the subject of a separate Commission report, rather than being addressed as an aspect of *Defining Death*.

The Commission's Study. The Commission's study of the "ethical and legal implications of the matter of defining death," as it was stated in the Congressional mandate, was also the first it completed. The study began with hearings in May and

June 1980 on the medical, ethical, religious, legal, and public policy aspects of the subject through written and oral presentations. The Commission also sponsored empirical investigations on the various outcomes of respirator support for patients in coma of both traumatic and nontraumatic origin, in order to have a rough idea of how frequently the determination of death by traditional measures of heartbeat and respiration is rendered difficult by artificial means of support. It was this empirical study that highlighted for the Commissioners the importance of addressing the ethical implications of decisions to cease treatment, since most "hard cases" faced by clinicians involved patients who were failing to recover, not those who had ceased to have any brain functions.

The Commission's Report. The Commission concluded that the necessary changes in the law, as well as the desirable goal of "uniformity" contemplated by its mandate, could best be achieved through statutory revision of the law. In its report the Commission noted that:

(1) Recent developments in medical treatment necessitate a restatement of the standards traditionally recognized for determining that death has occurred.

(2) Such a restatement ought preferably to be a matter of statutory law.

(3) Such a statute ought to remain a matter for state law, with Federal action at this time being limited to areas under exclusive Federal jurisdiction.

(4) The statutory law ought to be uniform among the several states.

(5) The "definition" contained in the statute ought to address general physiological standards rather than medical criteria and tests, which will change with advances in biomedical knowledge and refinements in technique.

(6) Death is a unitary phenomenon that can be accurately demonstrated either on the traditional grounds of irreversible cessation of heart and lung functions or on the basis of irreversible loss of all functions of the entire brain.

(7) Any statutory "definition" should be kept separate and distinct from provisions governing the donation of cadaver organs and from any legal rules on decisions to terminate life-sustaining treatment.

To embody these conclusions in statutory form, the Commission worked with the major professional bodies in medicine, law, and legislative reform to develop a new proposed statute. The American Bar Association, the American Medical Association, and the National Conference of Commissioners on Uniform State Laws joined the Commission in endorsing the Uniform Determination of Death Act, to replace their previous, separate proposals:

An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards.

The Commission recommended the adoption of this statute in all jurisdictions in the United States. The proposal recognizes that the traditional means to determine death will continue to be applied in the overwhelming majority of cases. In those instances in which artificial means of support require direct evaluation of the functions of the brain, the statute would recognize the use of accepted medical procedures.

As an aid to the implementation of the proposed statute, the Commission also published *Guidelines for the Determination of Death* as an appendix to its report. These were developed by a group of over 50 medical and scientific consultants representing a wide range of medical specialties. The Guidelines represent a distillation of current practice in regard to the determination of death, and are designed to be advisory. The purpose of the guidelines is to ensure that, to the greatest extent possible, a determination that death has occurred will:

- (1) eliminate errors in classifying a living individual as dead,
- (2) allow as few errors as possible in classifying a dead body as alive,
- (3) allow a determination to be made without unreasonable delay,
- (4) be adaptable to a variety of clinical situations, and
- (5) be explicit and accessible to verification.

Response to the Report. More than 6000 copies of the report were distributed by the Commission. Copies went to all members of Congress, appropriate offices in the Executive branch, state legislators and administrators in health-related positions, members of health professional and law reform organizations, members of the public on the Commission's mailing list, and medical and law school libraries. *Defining Death* quickly became a standard reference point in the public policy debate on this topic and has been widely cited in the scholarly literature.

The *Guidelines for the Determination of Death* were published in their entirety (with an accompanying editorial that praised them as a "landmark") in the November 13, 1981, issue of the *Journal of the American Medical Association*; they have subsequently been reprinted in a number of specialty journals and textbooks.

Since the Commission concluded that the matter of “defining” death should continue to be the province of state legislatures, with the Federal government reserving responsibility only for those areas of exclusive Federal jurisdiction, the focus of follow-up activities has been in the states rather than in the national legislature. In addition to supplying the report to all members of state health and judiciary subcommittees, the Commission staff testified before state committees when requested and supplied information to help coordinate state legislative activities. To date, the Uniform Determination of Death Act recommended by the Commission has been enacted in a dozen jurisdictions and is pending in as many more; Congress, however, has yet to respond to the recommendation for a statute to be applied in areas under Federal jurisdiction.

The Commissioners and staff have frequently been called upon as a resource on this issue, to clarify existing laws and to improve public understanding as certain cases received media attention (such as the Korean boxer Kim Duk Koo, who was declared dead on the basis of brain criteria and subsequently became an organ donor). Commission representatives were also able to discuss this issue in a number of national forums.

Informed Consent

The complexities of modern life make it difficult for individuals to be masters of their own fate. Perhaps in no sphere of everyday activity is this more acute than in health care....Traditionally, many cultures, including this one, have responded by according healers a unique deference and authority in their relationships with patients. Yet this authority is not, and has not been, absolute....American courts, supported by legal and ethical commentary, have articulated a legal doctrine of “informed consent” that requires health care practitioners not simply to seek the consent of their patients, but also, through a process of disclosure and discussion between practitioners and patients, to make such consents “informed.”

Making Health Care Decisions, pp. 15-16

The Issues. The Commission’s statutory mandate calls for a study of “the ethical and legal implications of the requirements for informed consent to participation in research projects and to otherwise undergo medical procedures.” In view of the considerable attention accorded to informed consent requirements in the research setting by the National Commission for the Protection of Human Subjects, as well as this Commission’s continuing attention to that subject in its separate Biennial Reports, the Commission decided to focus the “informed consent” project on medical treatment rather than upon research. In addition, the Commission—though

recognizing that “informed consent” is a doctrine developed by the law—decided that it could make a larger contribution on the subject if it did not limit its study solely to the legal aspects of informed consent. Instead, the broader issue of relationships between patients and health care providers in the delivery of health care was considered. This included an examination of the role of informed consent in promoting both communication between patients and health care professionals and “better” or “more autonomous” decisions by patients, as well as in improving therapeutic outcomes by increasing patient trust and decreasing provider anxiety over legal liability.

The Commission’s Study. A large number of witnesses were heard on the subject of enhancing patient participation in health care decisions; additional presentations and discussions focused on the issues raised by patients’ incapacity to participate in decisionmaking and on the role of families as surrogates. The Commission also received testimony from leaders in medicine, nursing, the humanities, and the social sciences on the need for better education of health care professionals about informed consent and on possible means of achieving it.

In order to learn more about informed consent as it occurs in practice, the Commission contracted for three empirical studies. Two studies involved observation and recording of interactions between health care professionals and patients in hospital settings as well as interviews with the people involved. The third was a national survey by Louis Harris and Associates of the views of physicians and members of the public regarding attitudes toward, experience with, and knowledge of informed consent, disclosure of information, and decisional authority in medical care. The results of all three studies are summarized in the report; a fuller description of the studies and the data obtained may be found in the first of two appendix volumes that accompany the report.

In the national survey—the first ever to compare simultaneously the attitudes on informed consent of patients and providers—telephone interviews were conducted with representative samples of 800 physicians and 1250 adults in the general public. The results showed that the public and physicians agree that patients have a right to all available information regarding their conditions and treatments and that the public universally desires such information. Moreover, the desire for information is universal and not specific to any age-group, sex, race, or social class. For example, 86% of the physicians believed most patients want a candid assessment of their diagnosis and prognosis, and 94% of the public reported they wanted to be told everything about their condition and treatment, even if it was unfavorable. However, when faced with a sick patient—such as one with a fully confirmed diagnosis of advanced lung cancer—physicians reported being

unwilling to be candid. Only 13% said they would "give a straight statistical prognosis for his class of disease."

Further, the proportion of physicians who reported discussing certain matters with their patients was generally greater than the proportion of patients who reported that their physicians do so. For example, while 98% of the physicians said they usually discuss diagnosis and prognosis with their patients, only 78% of the public reported that their physicians usually explained this to them. Likewise, 84% of the physicians claimed that they usually discuss the pros and cons of the recommended treatment, compared with 68% of the public who said their physician usually explains this to them.

The two observational studies examined the interaction of patients and health care professionals in various hospital settings. The results of both studies reveal that the actual practice of informed consent is not as close to the ideal as the results of the Harris survey suggest. In one study, which involved treatment refusals that the investigators subsequently discussed with the patients, refusals were generally triggered by the provision of too little (rather than too much) information. The second study examined whether the nature of the physician/patient interaction varied in several settings. Thus, the investigators compared the consent process for inpatients and outpatients, medical and surgical patients, and patients with acute versus chronic illness. With the exception of patients with chronic illness, the study showed that physician/patient communication in practice bore little relation to "informed consent" as envisioned by law.

The Commission's Report. *Making Health Care Decisions* traces the history of informed consent in the law and in medical practice and briefly sketches recent changes in the nature of health care and in society's expectations for the patient-professional relationship. As a group on bioethics, the Commission gave special attention to the values underlying informed consent.

The Commission discussed the customarily accepted ethical and legal obligations of health care professionals against a backdrop of what is known about actual practice, including the findings of its own empirical studies. The report also explored several means to bring goals and realities closer together. Attention was directed to innovative approaches in patient-



professional communication and decisionmaking that appear to be practically as well as theoretically sound. Legal rules, along with professional attitudes and behavior as they are shaped by education and training, were examined for their potential to provide patients with an effective basis to participate in decisionmaking. Finally, since certain people are unable to make some or all decisions on their own behalf, the Commission set forth principles and procedures for health care decisions that others must make for patients who lack decisionmaking capacity.

The Commission's findings and conclusions on this subject can be summarized as follows:

(1) Although the informed consent doctrine has substantial foundations in law, it is essentially an ethical imperative.

(2) Ethically valid consent is a process of shared decision-making based upon mutual respect and participation, not a ritual to be equated with reciting the contents of a form that details the risks of particular treatments.

(3) The literature about informed consent often portrays it as a highly rational process, suitable primarily for intelligent, highly articulate, self-aware individuals. The Commission found, however, a universal desire for information, choice, and respectful communication about decisions—for all patients, in all health care settings.

(4) Informed consent is based upon the principle that competent individuals are entitled to make health care decisions based upon their own personal values and in furtherance of their own personal goals. However, patient choice is not absolute:

- Patients are not entitled to insist that health care practitioners furnish them services when to do so would breach the bounds of acceptable practice or violate a professional's own deeply held moral beliefs or would draw on a limited resource to which the patient has no binding claim.
- In order to promote self-determination and patient well-being, individuals should be presumed to have decisionmaking capacity; only in a small minority of cases should incapacity disqualify a patient from making a decision regarding health care.
- Alternative arrangements should be made for decisionmaking on behalf of individuals who lack substantial capacity to make their own decisions; incapacity should be viewed, however, as specific to each particular decision.
- Persons lacking decisional capacity should be consulted about their own preferences, to the extent feasible, out of respect for them as individuals.

(5) Health care providers should not ordinarily withhold unpleasant information simply because it is unpleasant.

(6) Achieving the goal of shared decisionmaking based upon mutual respect is ultimately the responsibility of individual health care professionals. However, health care institutions such as hospitals also have important roles to play in fostering the process.

(7) Patients should have access to the information they need to help them understand their conditions and make treatment decisions.

(8) Improvements in the relationship between health care professionals and patients must come not primarily from the law but from changes in the teaching, examination, and training of health care professionals.

(9) Family members are often of great assistance to patients in helping them to understand information about their condition and in making decisions about treatment. Their involvement should be encouraged to the extent compatible with respect for the privacy and autonomy of individual patients.

(10) In order to promote a greater commitment of time to the process of shared decisionmaking, reimbursement schedules for all medical and surgical interventions should take account of the time necessarily spent in discussion with patients.

(11) To protect the interests of patients who lack decision-making capacity:

- Decisions made by others should, when possible, replicate those the patients would make if they were capable; when that is not feasible, the decisions of surrogates should protect the patients' best interests.
- Health care institutions should consider using mechanisms such as "ethics committees" for review and consultation regarding decisionmaking for those who lack the capacity to decide.
- State courts and legislatures should consider making provision for advance directives through which people may designate others to make health care decisions on their behalf and/or give instructions about their care should they become incapacitated.

Response to the Report. The Commission's report on informed consent, which was widely distributed to medical and nursing schools, as well as to scholars and teachers in related fields, struck a responsive chord, coming at a time when educators seem worried about the future direction of education and training of health care professionals. Particularly in medical education, concerns have been voiced increasingly about the large amounts of time students must devote to

absorbing a complex and overwhelming volume of scientific details. Some educators told the Commission that this current emphasis dehumanizes prospective physicians, resulting in practitioners who may lack sensitivity or who may overemphasize the importance of technological solutions to human problems.

Such concerns are now the subject of a study by a panel of the Association of American Medical Colleges (AAMC). In a first-year progress report of this three-year study, the panel identified many issues that parallel those in the Commission's study. The AAMC plans to continue to assess ways in which undergraduate institutions and medical schools might improve the essential knowledge and personal communication skills of future physicians.

The Commission learned that *Making Health Care Decisions* has already been found useful as teaching material in medical and nursing school classes. The Commission also provided copies to groups such as the National Council on Patient Information and other private and public organizations that are working to break down barriers of communication between health care providers and their patients.

The extensive data generated by the studies contracted by the Commission were welcomed by scholars in the field as a rich resource for further study. The Commission's survey of physicians and the public—which revealed some startling conclusions and contradicted common assumptions about patients' desire for information—also received widespread attention in the public press, confirming that this subject is of much more than academic concern.

Genetic Screening and Counseling

The rapid advances now occurring in genetic screening techniques and the increased resources devoted to genetic counseling give Americans new opportunities to understand their biological heritage and to make their health care and reproductive plans accordingly.

Screening and Counseling for Genetic Conditions, p. 1

The Issues. The Commission's mandate regarding genetic screening directed the Commission to undertake studies of the ethical and legal implications "of voluntary testing, counseling, and information and education programs with respect to genetic diseases and conditions, taking into account the essential equality of all human beings, born and unborn."

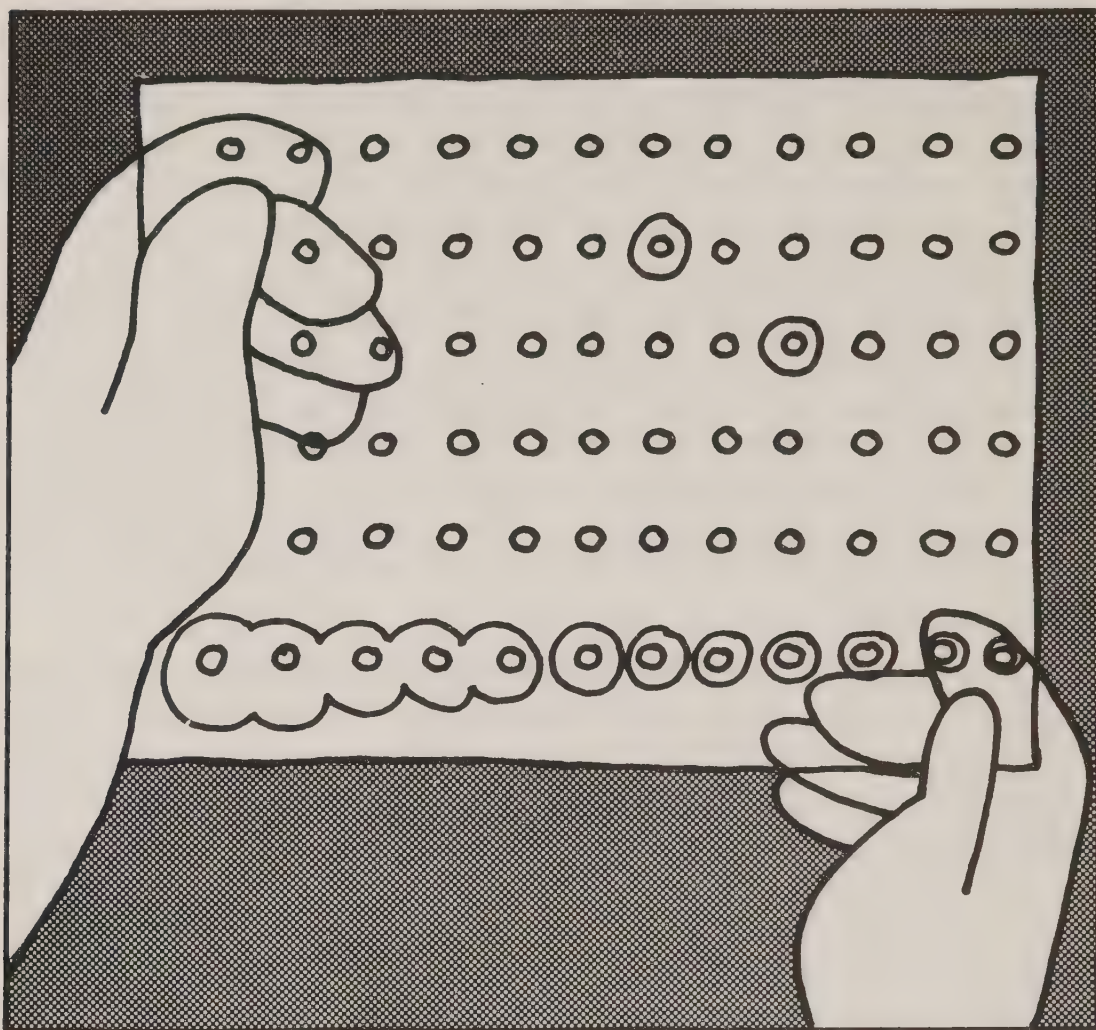
Genetic screening may be undertaken either to permit medical intervention or to provide information about reproductive choices. Genetic screening of the first type—that is, to uncover a person's need for medical care—is similar to other types of screening (such as routine blood pressure or tuberculin

tests) in that the goal is to determine whether remedial or preventive health care is needed. Genetic screening to provide information for reproductive decisions, on the other hand, differs from other routine tests in that the information produced is often relevant to medical decisions by individuals other than the person screened. The information provided—and the decisions based on it—have significance not only for people's own health, but also for the health of their children. Genetic counseling is an individualized process in which a specialist in medical genetics confers with an individual, a couple, or sometimes a group seeking additional information or assistance. It helps people with a potential or manifest genetic problem understand and, as far as possible, adjust to genetic information; when necessary, it aids them in making decisions about what course to follow.

The Commission's Study. At the Commission's first hearing on genetic screening, in May 1981, witnesses described screening for several serious inheritable conditions, including Tay-Sachs disease, sickle-cell anemia, phenylketonuria (PKU), and neural tube defects. The Commission also heard about recent research suggesting that prenatal or carrier screening tests for cystic fibrosis (CF), the most common lethal genetic disease in the United States, may be available in the not-too-distant future. The Commission decided to examine past experience with screening programs and to explore the ethical aspects of genetic screening as a means of anticipating issues that will be raised by large-scale screening for CF.

To ensure that the Commission would make a useful contribution in illuminating the ethical principles that should underlie the formulation of public policy on genetic screening, Commission staff reviewed with governmental and nongovernmental experts related work they have undertaken or plan to conduct on the ethical and legal aspects of genetic screening. In the spring of 1982, a second hearing was held, focused on genetic counseling issues, at which time a panel of experts commented on a staff draft of the report. The panel consisted of a genetic counselor, the director of Federal genetic activities, a philosopher, and two pediatrician/geneticists. This project was also coordinated with the Commission's work on informed consent and access to health care.

The Commission's Report. In *Screening and Counseling for Genetic Conditions*, the Commission discussed the basic facts about past genetic screening and counseling efforts and then set forth a number of conclusions and recommendations on how education, screening, and counseling programs could take account of important ethical and legal concerns. In the report's final chapter, these points were applied to cystic fibrosis screening as a hypothetical test case; the issues that would be



of concern there could also be expected to arise regarding tests developed for other genetic conditions.

On the whole, the Commission found that advances in medical genetics have greatly enhanced health and well-being. Some programs could have less beneficial consequences if they are not limited in certain ways, but most are not matters for concern or controversy. The Commission's major conclusions fell into five categories.

Confidentiality

(1) Genetic information should not be given to unrelated third parties, such as insurers or employers, without the explicit and informed consent of the person screened or a surrogate for that person.

(2) Private and governmental agencies that use data banks for genetics-related information should require that stored information be coded whenever that is compatible with the purpose of the data bank.

(3) Genetic information should be released to relatives (or their physicians) without the patient's consent if and only if the following four conditions are met: (a) reasonable efforts to elicit voluntary consent to disclosure have failed; (b) there is a high probability both that harm will occur if the information is withheld and that the disclosed information will actually be used to avert harm; (c) the harm that identifiable individuals

would suffer if the information is not disclosed would be serious; and (d) appropriate precautions are taken to ensure that only the genetic information needed for diagnosis and/or treatment of the disease in question is disclosed.

(4) Law reform bodies, working closely with professionals in medical genetics and organizations interested in adoption policies, should urge changes in adoption laws so that information about serious genetic risks can be conveyed to adoptees or their biological families. Genetic counselors should mediate the process by which adoptive records are unsealed and newly discovered health risks are communicated to affected parties.

Autonomy

(5) Mandatory genetic screening programs are only justified when voluntary testing proves inadequate to prevent serious harm to the defenseless, such as children, that could be avoided were screening performed.

(6) Professionals should generally promote and protect patient choices to undergo genetic screening and counseling, although the use of amniocentesis for sex selection should be discouraged.

Knowledge

(7) Decisions regarding the release of incidental findings (such as nonpaternity) or sensitive findings (such as diagnosis of an XY-female) should begin with a presumption in favor of disclosure, while still protecting a client's other interests, as determined on an individual basis. In the case of nonpaternity, accurate information about the risk of the mother and putative father bearing an affected child should be provided even when full disclosure is not made.

(8) Efforts to develop genetics curricula for elementary, secondary, and college settings and to work with educators to incorporate appropriate materials into the classroom are commendable.

(9) Professional educators, working with specialty societies and program planners, should identify effective methods to educate professionals about new screening tests. Programs to train health professionals, pastoral counselors, and others in the technical, social, and ethical aspects of genetic screening deserve support.

Well-Being

(10) Screening programs should not be undertaken unless accurate results will be produced routinely and a full range of prescreening and follow-up services are available.

(11) A genetic history and, when appropriate, genetic screening should be required of men donating sperm for artificial insemination; professional medical associations should take the lead in identifying what genetic information

should be obtained and in establishing criteria for excluding a potential donor.

- Records of sperm donors are necessary, but should be maintained in a way that preserves confidentiality to the greatest extent possible.
- Women undergoing artificial insemination should be given genetic information about the donor as part of the informed consent process.

Equity

(12) Access to screening may take account of the incidence of genetic disease in various racial or ethnic groups within the population without violating principles of equity, justice, and fairness.

(13) Policies on the availability of a genetic service should be subjected to review by a broadly based process that is responsive to the full range of relevant considerations.

- The time has come for such a review of the common medical practice of limiting amniocentesis for “advanced maternal age” to women 35 years or older.

(14) Determination of issues such as which groups are at high enough risk for screening or at what point the predictive value of a test is sufficiently high requires ethical as well as technical analyses.

(15) Cost-benefit analysis can make a useful contribution to allocational decisionmaking; difficult ethical issues, however, must still be confronted.

Response to the Report. The release of the Commission’s study at the end of February 1983 was front-page news in the *New York Times* and other papers across the country. The Commission’s Chairman and Director discussed the Commission’s findings and conclusions on national television and radio programs. There was considerable public interest in the report; in addition to those on the regular mailing list, the report was distributed by the Commission to over 1500 other people, and supplies were quickly exhausted.

Differences in the Availability of Health Care

Health care can relieve pain and suffering, restore functioning, and prevent death; it can enhance good health and improve an individual’s opportunity to pursue a life plan; and it can provide valuable information about a person’s overall health. Beyond its practical importance, the involvement of health care with the most significant and awesome events of life—birth, illness, and death—adds a symbolic aspect to health care: it is special because it signifies not only mutual empathy and caring but the mysterious aspects of curing and healing. Furthermore, while people have some

ability—through choice of life-style and through preventive measures—to influence their health status, many health problems are beyond their control and are therefore undeserved....Finally, the incidence and severity of ill health is distributed very unevenly among people....Together, these considerations lend weight to the belief that health care is different from most other goods and services. In a society concerned not only with fairness and equality of opportunity but also with the redemptive powers of science, there is a felt obligation to ensure that some level of health services is available to all.

Securing Access to Health Care, pp. 11-12

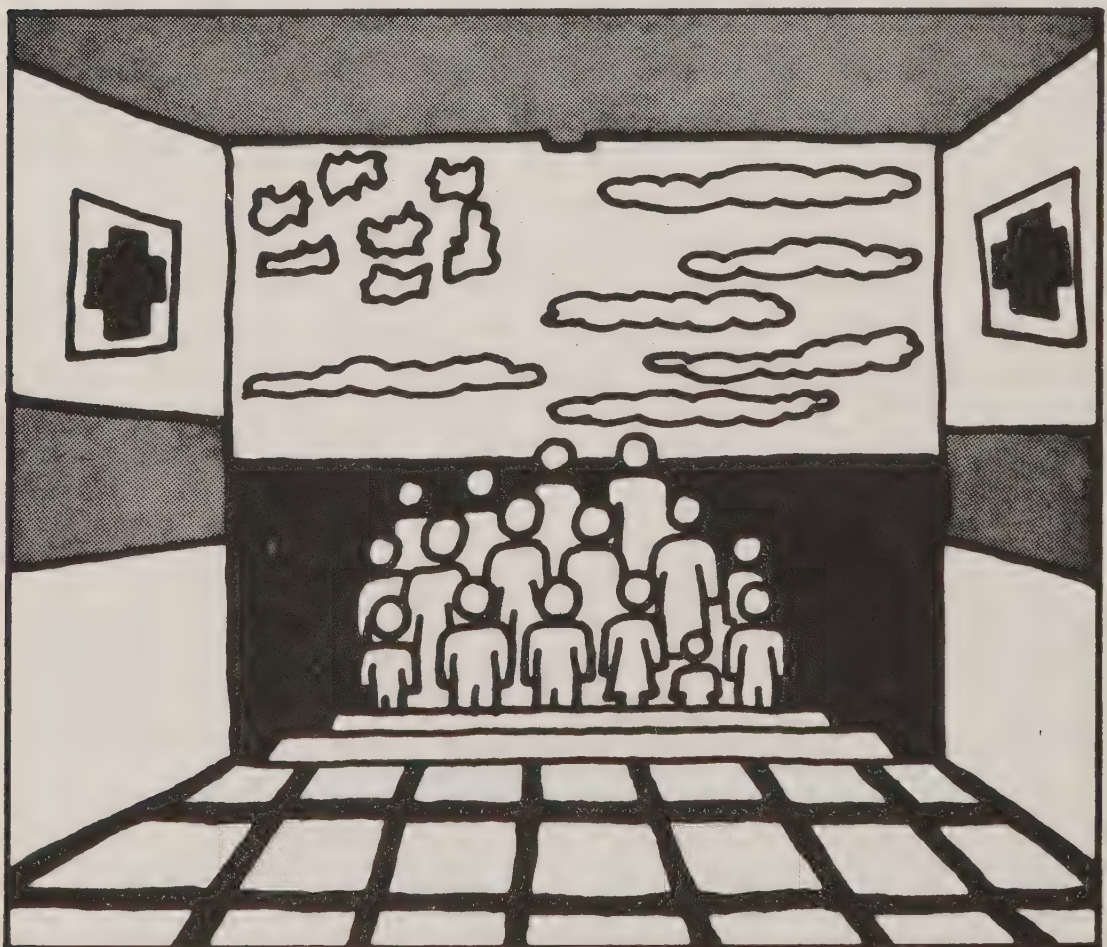
The Issues. In 1980, the nation spent an estimated \$247 billion on health care—an average of more than \$1000 for every citizen. Yet despite this enormous investment, all Americans do not share equally in the benefits of the health care system. Testimony presented to the Commission indicates that certain groups—the poor, minorities, the uninsured, and residents of inner-city and rural areas—are more likely to receive inadequate health services. Although most would agree that society has an ethical obligation to secure some level of care for those in need, past governmental programs and pronouncements by public officials do not reveal a consensus as to the level and nature of this commitment.

Government financing programs, like Medicare and Medicaid, as well as programs that provide care directly to veterans and the military and through local public hospitals, have greatly improved access to health care. These efforts, coupled with the expanded availability of private health insurance, have resulted in almost 90% of Americans having some form of health insurance coverage in normal economic times. Yet the patchwork of government programs and the uneven availability of private health insurance through the workplace has resulted in the exclusion of millions of people. In mid-1982, the Surgeon General observed that with rising unemployment, the percent of the population without health insurance coverage would rise rapidly, a prognosis confirmed by more-recent studies by the Congressional Budget Office. Many such people lack effective access to health care, and many more who have some form of insurance are unprotected from the severe financial burdens of sickness.

The Commission's Study. In pursuing its mandate to study the ethical implications of differences in the availability of health services, the Commission elected to step back from the current health policy debate in order to examine possible justifications for the conclusion that health care should, as a matter of national policy, be available to all. Which patterns of access should be considered equitable? And how can the

burdens encountered in striving to eliminate the inequities in access be fairly distributed?

At one meeting, the Commissioners explored in detail a number of philosophical issues in health care. In addition to reports by members of a panel of philosophers, who had been studying the subject for the Commission, witnesses from medicine and law joined in discussing the right to health care, the concept of adequate care, health care needs and deserts, and providers' and patients' freedom of choice. Another meeting dealt with ethical issues in the allocation of health care resources. The discussion focused on how decisions that limit available care are made within different delivery settings (hospitals and health maintenance organizations) and about various types of services (end-stage renal disease, adult and neonatal intensive care, and hypertension screening and treatment), as well as the role of third-party payors in this process. The hearing concluded with testimony about the implications that malpractice and regulatory law have for efforts to improve equity of access to health care.



The final hearing on this subject was held in Atlanta, where testimony was presented by members of the public who had found it difficult to secure or pay for health services, from physicians and a hospital administrator about problems in delivering health care to the poor, and from several health officials and the heads of voluntary organizations about access

patterns and policies in their states. The Commission also received the report of a study on insurance coverage and the use of health services, and it heard testimony on innovative solutions to the maldistribution of health care providers. Finally, while in Atlanta, the Commissioners visited a Federally supported primary care center that serves a largely low-income, urban neighborhood.

The Commission's hearings and site visit added personal and immediate experiences to the wealth of data provided by analyses undertaken for the Commission and by published studies, including several national surveys on health status and the use of health services related to demographic characteristics such as race, income, and place of residence. Over the course of a number of subsequent meetings, at one of which a number of experts provided comments on a draft of the report, the Commissioners refined successive versions of the report, before adopting it (by a vote of ten to one) in December 1982. (The report was released at the end of March 1983, after the present report was in press.)

The Commission's Report. In *Securing Access to Health Care*, the Commission did not propose any new policy initiatives. Rather, it tried to provide a framework within which debates about health policy might take place, in the hope it would aid policymakers in considering whether some proposals do a better job than others of securing health care on an equitable basis. The Commission summarized its conclusions as follows:

(1) The Commission concludes that society has an ethical obligation to ensure equitable access to health care for all. This obligation rests on the special importance of health care, which derives from its role in relieving suffering, preventing premature death, restoring functioning, increasing opportunity, providing information about an individual's condition, and giving evidence of mutual empathy and compassion. Furthermore, although lifestyle and the environment can affect health status, differences in the need for health care are for the most part undeserved and not within an individual's control.

(2) The societal obligation is balanced by individual obligations. Individuals ought to pay a fair share of the cost of their own health care and take reasonable steps to provide for such care when they can do so without excessive burdens. Nevertheless, the origins of health needs are too complex, and their manifestation too acute and severe, to permit care to be regularly denied on the grounds that individuals are solely responsible for their own health.

(3) Equitable access to health care requires that all citizens be able to secure an adequate level of care without excessive burdens. Discussions of a right to health care have frequently been premised on offering patients access to all

beneficial care, to all care that others are receiving, or to all that they need—or want. By creating impossible demands on society's resources for health care, such formulations have risked negating the entire notion of a moral obligation to secure care for those who lack it. In their place, the Commission proposes a standard of "an adequate level of care," which should be thought of as a floor below which no one ought to fall, not a ceiling above which no one may rise.

Equitable access also means that the burdens borne by individuals in obtaining adequate care (the financial impact of the cost of care, travel to the health care provider, and so forth) ought not to be excessive or to fall disproportionately on particular individuals.

(4) When equity occurs through the operation of private forces, there is no need for government involvement, but the ultimate responsibility for ensuring that society's obligation is met, through a combination of public and private sector arrangements, rests with the Federal government. Private health care providers and insurers, charitable bodies, and local and state governments all have roles to play in the health care system in the United States. Yet the Federal government has the ultimate responsibility for seeing that health care is available to all when the market, private charity, and government efforts at the state and local level are insufficient in achieving equity.

(5) The cost of achieving equitable access to health care ought to be shared fairly. The cost of securing health care for those unable to pay ought to be spread equitably at the national level and not allowed to fall more heavily on the shoulders of particular practitioners, institutions, or residents of different localities.

(6) Efforts to contain rising health care costs are important but should not focus on limiting the attainment of equitable access for the least well served portion of the public. The achievement of equitable access is an obligation of sufficient moral urgency to warrant devoting the necessary resources to it. If the nation concludes that too much is being spent on health care, it is appropriate to eliminate expenditures that are wasteful or that do not produce benefits comparable to those that would flow from alternate uses of these funds. But measures designed to contain health care costs that exacerbate existing inequities or impede the achievement of equity are unacceptable from a moral standpoint.

Life-Sustaining Treatment

Death comes to everyone. To a few, it comes suddenly and completely unexpectedly, but to most, it follows an opportunity for leave-taking and for directing to some extent the mode and timing of death. Virtually all people

who die in this country will have been under treatment by health care professionals who have, especially in the last four decades, developed powerful means to forestall death...Physicians realize, of course, that the mission of vanquishing death is finally futile, but often they and their patients are quite determined to do all that is possible to postpone the event. Sometimes this objective so dominates care that patients undergo therapies whose effects do not actually advance their own goals and values. Specifically, the drive to sustain life can conflict with another fundamental (and arguably more venerable) objective of medicine—the relief of suffering...The attempt to postpone death should at times yield to other, more important goals of patients.

Deciding to Forego Life-Sustaining Treatment, pp. 15-16

The Issues. In responding to its legislative mandate to study the “definition” of death, the Commission was struck by the depth of public concern about life-sustaining treatment of patients who are dying or permanently unconscious. The general public and the news media—as well as health care professionals—were very interested in the Commission’s responses to a number of specific policy problems such as care for patients in Karen Quinlan’s situation, “living will” legislation, hospice care, and “do not resuscitate” orders. Feeling a responsibility to address these issues, the Commission decided to undertake a separate study of the ethical and legal implications of decisions to forego (that is, either to halt or not to initiate) life-sustaining treatment.

Today, for almost any life-threatening condition, some intervention is capable of delaying the moment of death. The frequency of dramatic breakthroughs in medical care—insulin, antibiotics, resuscitation, chemotherapy, dialysis, and transplantation, to name but a few—has made it possible to retard and even to reverse many conditions that were until recently regarded as fatal. Matters that were once the province of fate have now become a matter of human choice, a development that has profound ethical and legal implications.

Moreover, medical technology often renders patients less able to communicate or to direct the course of treatment. Even for mentally competent patients, others must usually assist or acquiesce in any decision to forego life-sustaining treatment. Conflicting values between physicians and patients, between patients and their families, or among family members are not uncommon. When joined with the confusion that surrounds issues of rights and liabilities, it is hardly surprising that judges have been called upon more often than previously to serve as the final bioethical arbiters in decisions to forego life-support measures. Consequently, it appeared to the Commission that

attempting to clarify the rights, duties, and liabilities of all concerned could be most valuable—drawing on the thinking of health professionals as well as ethical and legal commentators and concluding with appropriate guidance for hospitals, legislatures, and courts.

The Commission's Study. The Commission's study was undertaken not merely because of the report on defining death but also because of the relationship of this subject to the other studies that were being prepared. Deciding about life-sustaining therapy is one instance—and a particularly important one—of applying the principles of decisionmaking in medicine, which was the subject of *Making Health Care Decisions*. Such decisions are also constrained by considerations of justice and equity in the allocation of often scarce and expensive resources, a subject discussed in *Securing Access to Health Care*. The report on decisions about life-sustaining treatment thus represented an effort to apply the conclusions of two Commission reports to a particular area of current concern, while also responding to some of the tensions highlighted in *Defining Death*.

The five hearings on this report and those on the four allied reports overlapped to some extent; for example, the February 1982 hearing on "competence" in health care decisionmaking was relevant to both this study and the one on informed consent, as were hearings on resuscitation orders and the care of permanently unconscious patients. The Commissioners also heard testimony on the special problems arising in neonatal intensive care units and the medical, ethical, and legal aspects of life-sustaining treatment. Altogether, this study appeared on the Commission's agenda on more occasions than any other, a reflection of the difficulty of the issues raised and of the scope of the Commission's inquiry.

The Commission's Report. Building on a central conclusion of the report on informed consent—that decisions about health care must ultimately rest with competent patients—the Commission examined the situations in which a patient's choice to forego life-sustaining therapy may be limited on moral or legal grounds. In addition to providing clarification of the issues, the report suggested appropriate procedures for decisions regarding both competent and incompetent patients and scrutinized the role of various public and private bodies in shaping and regulating the process. *Deciding to Forego Life-Sustaining Treatment* did not judge any particular future case nor did it seek to provide a guidebook of morally correct choices for patients and health care providers who are facing such a decision. Rather, the Commission tried to illuminate the strengths and weaknesses of various considerations and various instruments of public policy. Clarifying the relevant

considerations and prohibitions may help decisionmakers even while it forces them to confront painful realities more directly.

The first half of the Report examined the considerations common to all decisionmaking about life-sustaining therapy. The social context of the report was highlighted by attention to the historical, cultural, and psychological dimensions of the subject. Although shared decisionmaking between provider and patient is the objective, the Commission pointed out that, particularly for seriously ill patients, constraints on choice arise when patients are inadequate decisionmakers; other



constraints are imposed by the community's need to ensure that life is protected and that wrongful death is deterred and punished. The report scrutinized the distinctions that have commonly been made between acceptable and unacceptable foregoing of treatment and suggested how such distinctions, though often not in themselves of ethical importance, can still be useful in sound decisionmaking. The report paid particular attention to limitations on patients' choices that result from the actions of family members and care-giving professionals, from society's pursuit of equitable allocation of resources, and from the policies and practices of health care institutions (hospitals, nursing homes, and hospices), which are typically the settings where these many forces come together.

The report then considered several groups of patients whose situations raise special public policy concerns. The Commission first suggested certain concepts and procedures relevant to decisionmaking for incompetent patients generally, including advance directives (such as "living wills"), intra-institutional review (such as ethics committees), and court proceedings. It then turned to two groups of incompetent patients—those who have permanently lost all consciousness and seriously ill newborns. Finally, the report considered when and why "orders not to resuscitate" may be written for hospitalized patients whose hearts stop beating, and recommended institutional policies on such orders.

The Commission's conclusions in *Deciding to Forego Life-Sustaining Treatment* are numerous and deal with complex issues of law, medicine, ethics, and social policy in a manner

that cannot be paraphrased or summarized without introducing the possibility of significant distortion, misinterpretation, or over-simplification. In general, the conclusions describe the appropriate roles and responsibilities of individuals, institutions, and framers of public policy (including the courts) in three important areas—assisting patients and their families in making difficult decisions, resolving different views among interested parties, and setting limits on the choices that may be accepted under certain circumstances.

Throughout the report the Commission emphasized the importance of:

- respecting the choices of individuals competent to decide to forego even life-sustaining treatment;
- providing mechanisms and guidelines for decision-making on behalf of patients unable to do so on their own;
- maintaining a presumption in favor of sustaining life;
- improving the medical options available to dying patients;
- providing respectful, responsive, and supportive care to patients for whom no further medical therapies are available or elected; and
- encouraging health care institutions to take responsibility for ensuring that adequate procedures for decisionmaking are available for all patients.

The Commission also concluded that the choices of patients, their families, and health care providers may legitimately be limited in certain ways on grounds of public policy, professional judgment, and considerations of resources scarcity.

Response to the Report. This study generated the greatest public response of any the Commission produced. Even before the report was issued, over 1000 individuals requested draft copies, based upon media attention during the Commission's consideration of the topic. The report received prominent and respectful coverage in the new and editorial columns of papers across the country and in journals for specialized audiences, and the Commission's Chairman and senior staff appeared on national television and radio to discuss the report. Portions of the report have already been incorporated in medical and nursing school curricula and have been studied by those responsible for framing the policies of hospitals, nursing homes, and other health care institutions.

Privacy and Confidentiality

The Issues. The Commission was mandated by its enabling legislation to undertake a study of "the ethical and legal implications of current procedures and mechanisms designed

(i) to safeguard the privacy of human subjects of behavioral and biomedical research, (ii) to ensure the confidentiality of individually identifiable patient records, and (iii) to ensure appropriate access of patients to information contained in such records."

Previous Commissions and legislative bodies had already considered many of the problems posed by the dissemination of medical information, and a medical records privacy act was pending in Congress during the first year of the Commission's work. When, in late 1980, the 96th Congress failed to pass that act the Commissioners turned their attention to this subject.

The Commission's Study. The Commissioners received a briefing on privacy at their first meeting in January 1980, at which an overview of principal issues was presented. A comprehensive hearing on the subject was held in March 1981, during which the Commission explored the relevant ethical issues and discussed several ways of fulfilling its mandate.

The Commission heard testimony from the former general counsel to the Privacy Protection Study Commission, who described that group's work from 1974 to 1977; the counsel to the Royal Commission of Inquiry into the Confidentiality of Medical Records in Ontario, which issued its final report in 1980; and the counsel to the National Commission on the Confidentiality of Medical Records, a private group that was active in the late 1970s and that served as a focal point for consumer complaints. In addition, a special assistant to the Director of the National Institutes of Health described privacy issues associated with the use of medical records in research. Finally, the former counsel to the Minority for the U.S. Senate's Committee on Governmental Affairs discussed efforts in the 96th Congress to pass legislation protecting the confidentiality of medical records.

After considering the testimony of these expert witnesses, the Commissioners decided the issues of privacy and confidentiality could be best addressed by considering them as follows:

- issues relating to the privacy of research records and to the use of patient records in research would be incorporated into the biennial reports on the protection of human research subjects;
- issues relating to the access to medical records by patients and third parties (such as insurance companies and employers) would be incorporated into the report on informed consent; and
- matters regarding records relating to genetic information would be included under the study of genetic screening and counseling.

In addition, the Commissioners requested an analysis of the major philosophical issues that had been identified,

although they specified that such a study should not delay other Commission studies, as it was apparent that the others were more likely to make significant new contributions to public policy on bioethical issues.

In March 1982, the Commissioners reviewed the consultants' report on the philosophical aspects of privacy and confidentiality of medical records, accompanied by a statutory appendix summarizing current U.S. laws on the subject. The wide-ranging paper considered the subject from the diverse perspectives of law, philosophy, economics, politics, and public opinion.

Before examining the special nature of privacy and confidentiality in relationship to health care, the consultants defined the terms:

Privacy is a concept that applies to *individuals* with respect to others; confidentiality is a concept that applies only to *relationships* between or among persons and institutions. Privacy concerns control over access and disclosure in the first instance; confidentiality concerns only redisclosure of information previously disclosed. Privacy is normally controlled by the individual; confidentiality by the person for/to whom the individual's privacy is relinquished.

They found that although not absolute, these values are fundamental and morally important in that acceptance of and respect for them underlies the formation of the doctor-patient relationship. They also identified other values—such as knowledge, truth, or safety—that may come in conflict with privacy and confidentiality.

In health care settings, patients often must relinquish control over not only their bodies but also their sensations, thoughts, and even feelings. Within the confines of the physician-patient relationship, privacy is given up—either as part of a patient's ritual response to the relationship or at a physician's explicit (and sometimes quite insistent) urging. The justification for this relinquishing of control—that is, the ethical value on which it rests—is the promotion of well-being for the patient. The process of shared decisionmaking about health care that the Commission advocated in its report on informed consent depends on full and open communication between professional and patient. Therefore, the patient must drop the barriers of privacy and share verbal and physical information with the practitioner if the patient is to derive maximum benefit from the treatment.

To encourage this process, patients are assured that the information they disclose will not be repeated to others. Confidentiality in health care is intended to protect patients against harm to reputation or personal relationships, threats against employment, or exploitation by public agencies or

private interests. The protection of confidentiality thus reflects respect for persons, the same value that underlies patient autonomy and self-determination.

It is apparent that however valuable privacy and confidentiality may be in health care, there are competing values that may sometimes outweigh them. While emphasizing the connection between consent and confidentiality in *Making Health Care Decisions*, the Commission also recognized that there are circumstances when other goals should predominate. Likewise, in *Screening and Counseling for Genetic Conditions*, the Commission concluded that under certain, limited circumstances a genetic counselor may be justified in overriding a patient's desire for confidentiality in order to protect identifiable relatives from severe and otherwise unavoidable harm.

There are many points of tension—and many issues in contention—in the law and ethics of medical privacy today. Detailed empirical exploration beyond that which the Commission could undertake in light of its other studies would be indispensable in clarifying and possibly resolving these issues. For example, research scientists are concerned that present legal rules exalt privacy at the expense of important scientific findings that could benefit large numbers of people. But would an exception for a epidemiologist from the National Institutes of Health also apply to a union representative who want to examine workers' medical records to gather grounds for filing a complaint against—and possibly closing—the factory where they work?

Although the construction of a set of statutory or administrative rules and procedures that rested on a firm ethical principle is too large a task to be undertaken here, the Commission found several basic points of agreement. In large part, the Commission hopes its identification of these points here will serve to encourage health care providers to give greater attention to this subject.

(1) Respect for patients' legitimate expectations of privacy is an important part of ethical health care practices, as well as the foundation on which a relationship of mutual trust and benefit can be built between patient and professional.

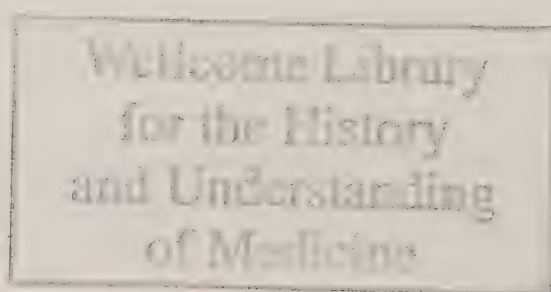
(2) Health care institutions and providers are urged to educate the public about their expectations and practices on private medical matters.

- In particular, patients need to be better informed about the scope of confidentiality and to be given the opportunity to give waivers for specific information rather than blanket waivers.
- Specific warnings should be made if disclosures of patient information are anticipated without prior consent.

(3) Instances of unconsented disclosures are to be regarded as exceptions to the general norm of confidentiality and require special justification, such as an important public purpose.

(4) When information is provided based upon a general consent by a patient (for example, permission for a hospital to send records to a third-party payor), no more information should be disclosed than is necessary for the functions to be performed by the third party.

- Efforts should be made to permit patients to review for accuracy any records to be disclosed.
- Third-party recipients of confidential information are encouraged to find economical methods of notifying patients whose records they are requesting or when they plan to pass along individually identifiable information to other persons or organizations.



Studies on Biomedical and Behavioral Research

3

The lines between biomedical practice and research are not always clear. One area investigated by the Commission illustrated how these lines are being crossed today, as the many diagnostic and therapeutic applications of genetic engineering are discovered. In *Splicing Life* (1983), the Commission reported on the current developments in genetic engineering as they apply to human beings and considered the social and ethical implications of this rapidly evolving field. As with any research that involves human subjects, careful attention must be paid to both the immediate and the long-term impacts. Issues such as these were taken up by the Commission in the two Biennial Reports required by its Congressional mandate, *Protecting Human Subjects* (1981) and *Implementing Human Research Regulations* (1983). The research side of the Commission's mandate was also addressed through a report on *Compensating for Research Injuries* (1982), in a cosponsored workshop on *Whistleblowing in Biomedical Research* (the proceedings of which were published in 1982), and in *The Official IRB Guidebook* (1983), a project on which the Food and Drug Administration and the Office for Protection from Research Risks, NIH, cooperated.

Genetic Engineering

The recently acquired capability to manipulate the genetic material of all living things is an important—even revolutionary—advance in the trajectory of human knowledge. But, like revolutionary insights of the past that enriched understanding, it also unsettles notions that once seemed fixed and comfortable.

Splicing Life, p. 7

The Issues. Using recombinant DNA and other techniques of molecular biology and cell manipulation (popularly known as gene splicing), genetic material from one organism can be inserted into an organism of a different species. The process has already demonstrated its importance in facilitating the production of heretofore rare drugs and in improving agriculture. The potential applications of these techniques in the diagnosis and treatment of human conditions resulting from genetic defects are enormous.

The genetic makeup of organisms once seemed inviolable, but now the rapid advances in genetic engineering are revolutionizing human beings' perception of their limits. The profound implications of the ability to manipulate genes led the General Secretaries of the National Council of Churches, the Synagogue Council of America, and the United States Catholic Conference to write to President Carter in June 1980 expressing concern that "no government agency or committee is currently exercising adequate oversight or control" over genetic engineering. The three religious leaders requested that a way be provided "for representatives of a broad spectrum of our society to consider these matters and advise the government on its necessary role."

The Commission considered the issues raised in the letter at its September 1980 meeting and learned that no government agency had analyzed the social and ethical implications of genetic engineering. It also noted that the public concern is in part a result of confusion about foreseeable applications of the technology. Although the Commission was already responsible for a demanding schedule of reports, the issues involved were deemed very important, and the Commissioners decided to add to its agenda a small study on the use of genetic engineering in human beings.

The Commission's Study. This study was seen as a first step in what ought to be a continuing public examination of the emerging questions posed by developments and prospects in the human applications of molecular genetics. The Commission decided that its initial response to the religious leaders' concerns about government oversight would be to survey governmental agencies about their activities in this field. With the aid of a special consultant, a review of the field was also prepared for the Commissioners.

To assist in preparing this Report, the Commission assembled a diverse group of consultants that included representatives from medicine and biology, philosophy and ethics, law, social policy, and the private industrial sector. These consultants held a series of meetings with Commissioners and staff on the direction of the Commission's work in this area and the issues to be addressed. A preliminary analysis of the issues was prepared for discussion by the Commission in July 1981.

This and subsequent drafts were submitted to members of the panel, and comments were also received from other scientists and expert observers of the developments of genetic engineering. In addition, several knowledgeable people were invited to discuss a draft report with the Commissioners at a hearing in July 1982.

The Commission's Report.

Splicing Life attempted first to clarify concerns about genetic engineering and to provide technical background intended to increase public understanding of the capabilities and potential of the technique. Next, it evaluated the issues of concern in ways meaningful for public policy and analyzed the need for an oversight mechanism.



To summarize, the Commission found that:

(1) Although public concern about gene splicing arose in the context of laboratory research with microorganisms, it seemed to reflect a deeper anxiety that work in this field might remake human beings, like Dr. Frankenstein's monster. These concerns seem to the Commission to be exaggerated. It is true that the genetic engineering techniques are not only a powerful new tool for manipulating nature—including means of curing human illness—but also a challenge to some deeply held feelings about the meaning of being human and of family lineage. But as a product of human investigation and ingenuity, the new knowledge is a celebration of human creativity, and the new powers are a reminder of human obligations to act responsibly.

(2) Genetic engineering techniques are advancing very rapidly. Two breakthroughs in animal experiments during 1981 and 1982, for example, bring human applications of gene splicing closer: in one, genetic defects have been corrected in fruit flies; in another, artificially inserted genes have functioned in succeeding generations of mammals.

(3) Genetic engineering techniques are already demonstrating their great potential value for human well-being. The aid that these new developments may provide in the relief of human suffering is an ethical reason for encouraging them.

- Although the initial benefits to human health involve pharmaceutical applications of the techniques, direct diagnostic and therapeutic uses are being tested and some are already in use.
- Use of the new techniques in genetic screening will magnify the ethical considerations already seen in that field because they will greatly enlarge the demand for, and even the objectives of, prenatal diagnosis.

(4) Many human uses of genetic engineering resemble accepted forms of diagnosis and treatment employing other techniques. The novelty of gene splicing ought not to erect any automatic impediment to its use but rather should provoke thoughtful analysis.

- Especially close scrutiny is appropriate for any procedures that would alter the genes passed on to patients' offspring.
- Interventions aimed at enhancing "normal" people, as opposed to remedying recognized genetic defects, are problematic; there is a danger of drifting toward attempts to "perfect" human beings once the door of "enhancement" is opened.

(5) Questions about the propriety of gene splicing are sometimes phrased as objections to people "playing God." The Commission is not persuaded that the scientific procedures in question are inherently inappropriate for human use. It does believe, nevertheless, that objections of this sort, which are strongly felt by many people, deserve serious attention and that they serve as a valuable reminder that great powers imply great responsibility. If beneficial rather than catastrophic consequences are to flow from the use of "God-like" powers, an unusual degree of care will be needed with novel applications.

(6) The generally very reassuring results of laboratory safety measures have led to a relaxation of the rules governing gene splicing research that were established when there was widespread concern about the potential risks of the research. Today those regulating gene splicing research operate from the assumption that most such research is safe, when conducted according to normal scientific standards; those opposing that position face the task of proving otherwise.

(7) The Recombinant DNA Advisory Committee (RAC) at the National Institutes of Health has been the lead Federal agency in genetic engineering. The time has now come to broaden the area under scrutiny to include issues raised by the intended uses of the technique rather than solely the unintended exposure from laboratory experiments. It would also be desirable for this "next generation" RAC to be independent of Federal funding bodies such as NIH, which is the major

Federal sponsor of gene splicing research, to avoid any real or perceived conflict of interest.

(8) The process of scrutiny should involve a range of participants with different backgrounds—not only the Congress and Executive Branch agencies but also scientific and academic associations, industrial and commercial groups, ethicists, lawyers, religious and educational leaders, and members of the general public. Several formats deserve consideration, including initial reliance on voluntary bodies of mixed public-private membership. Alternatively, the task could be assigned to this Commission's successor, as one among a variety of issues in medicine and research before such a body, or to a commission concerned solely with gene splicing. Whatever format is chosen, the group should be broadly based and not dominated by geneticists or other scientists, although it should be able to turn to experts for advice.

(9) The need for an appropriate oversight body is based upon the profound nature of the implications of gene splicing as applied to human beings, not upon any immediate threat of harm.

Response to the Report. The Investigations and Oversight Subcommittee of the House Science and Technology Committee, chaired by Representative Albert Gore, Jr., held hearings November 16-18, 1982, on genetic engineering, to provide a forum for the Commission's release of its report. The Committee received testimony from experts in biology, ethics, genetics, theology, philosophy, sociology, law, and other disciplines. The hearings were an occasion for a wide-ranging discussion of the implications of genetic engineering in humans. The witnesses were also asked by Chairman Gore to comment on the Commission report; they were virtually unanimous in their support of its recommendation for an oversight body, for a variety of reasons. Mr. Gore has indicated he will soon introduce legislation that would establish such a body. There was extensive press coverage of these hearings and of *Splicing Life*. For example, *U.S.A. Today* devoted its entire editorial page one day to the topic of genetic engineering; the evening of the Congressional hearings the subject was discussed on a half-hour television news program, the MacNeil/Lehrer Report; and the Commission's study was covered widely by other news media.

Compensation for Injured Subjects

The power of medicine to cure and prevent illnesses has increased enormously during the present century. All those having access to medical care have been the beneficiaries....An outstanding feature of contemporary medicine is its commitment to research and to the scientific application of research findings....New tech-

niques, unless they are adopted blindly, must be tested, and testing in turn requires not only laboratory and animal studies but also the use with human subjects of uncertain methods whose range of effects cannot be predicted precisely in advance. Risk is thus inherent in medical research, no matter how conscientious the investigator and careful the research.

Compensating for Research Injuries, p. 9

The Issues. The power of medicine both to cure and to prevent illnesses has increased enormously during the present century. Most of the advances in medicine have depended upon carefully conducted research, supported in large part by public funds. The research, in turn, often depends upon the willingness of human volunteers to agree to participate in studies that may present some degree of risk.

In research, as in other sectors of modern society, benefits to the community are thus achieved at the expense of a few. If those few experience tangible harm, the question arises whether they have a moral claim against the community for compensation. Since society at large both supports and benefits from the conduct of biomedical research, many have argued that there is a societal obligation to care for or “make whole” those who have been injured for the collective good.

Although untoward results of biomedical research appear to be few in number, they can be real and serious to those who are affected. The community is thus faced with questions of responsibility. Who is responsible for the welfare of those who are injured as a result of participating in research? What are they owed? If the subjects have willingly and knowingly assumed the risks, does that affect their moral claim for compensation? Is it possible to devise programs to compensate research subjects without opening a Pandora’s box—an administrative and fiscal nightmare?

The Commission’s Study. The Commission decided at its first meeting to take up the question of providing compensation for research-related injuries because the subject was of concern to a number of Federal agencies conducting or supporting research with human subjects in addition to the Department of Health and Human Services, where the request for the study originated. The topic was discussed at full-day hearings in May and September 1980 and in January 1981. Senior staff of the Commission worked with a special consultant who has an expert in both public and private insurance programs and with officials of the insurance industry to explore the feasibility of developing a response in the private sector to the perceived coverage needs. A preliminary draft report was widely disseminated and revised in light of comments from individuals, former research subjects, and interested groups, such as the University Risk Management

and Insurance Association and the Association of American Medical Colleges.

Although it found that the sponsors and regulators of research (such as NIH and FDA) do not have information available on the occurrence of harm, the Commission developed data on the subject directly from several research centers that have compensation programs. These reports included considerable information on the number of research subjects covered, the number of subject-days involved, the nature of the research covered, and the nature and incidence of injuries reported. The number of claims filed in these programs is quite small. Although a few serious problems were reported, adverse effects were usually transient and minor (such as skin rashes, stomach upsets, headaches, or dizziness).

The Commission also received reports from legal scholars on the extent to which remedies currently available through the courts can provide redress for research-related injuries. In addition, a health policy analyst was asked to study several Federal programs designed to provide either health care or benefits (for example, Social Security Disability Insurance, Black Lung Program, Federal workers' compensation, and veterans serviced-connected disability benefits) to learn about administrative difficulties, cost containment, and the apparent trend of such programs to expand beyond the limits originally contemplated. Toward this same end, the Commission received materials and reports on programs in other countries that provide compensation for injured research subjects.

An important component of the Commission's study of this problem was a reexamination of the ethical arguments for and against the existence of a societal obligation to compensate for research injuries. Several philosophers presented their views on this subject and the Commission reviewed the ethical arguments that had been presented to an earlier task force convened by the Secretary of Health, Education and Welfare. The Commission considered the arguments of professional societies and research administrators that whatever moral claims may arise on behalf of participants in nontherapeutic research (from which subjects derive no health benefits), no such claim attaches when patients participate in clinical trials of new therapies, from which they hope and can expect to derive direct medical benefit.

Finally, the Commission noted that in their *Proposed International Guidelines for Biomedical Research Involving Human Subjects*, the World Health Organization and the Council for International Organizations of Medical Sciences had recently concluded:

Reports of accidental injury to subjects...are excessively rare....However, any volunteer subjects involved in medical research who may suffer injury as a result of

their participation are entitled to such financial or other assistance as would compensate them fully for any temporary or permanent disability. (Guidelines 30 and 31)

Experimental subjects should not, in giving their consent to participation, be required to waive their rights to compensation in the case of an accident; nor should they be required to show negligence or lack of a reasonable degree of skill on the part of the investigator....This is particularly necessary in the case of externally sponsored research when the subjects are not protected by social security measures. (Guideline 32)

The Commission's Report. The conclusions in favor of a general program of compensation that had been reached in 1977 by the HEW Secretary's Task Force on Compensation for Injured Research Subjects were called into question by the Commission for at least three reasons. First, the frequency and severity of research-related injuries are unclear; second, a number of practical administrative difficulties appear likely under the concepts endorsed by the HEW Task Force; and, third, the moral claims of injured subjects appear less convincing in many circumstances (particularly in clinical trials) than acknowledged by the Task Force.

In light of the testimony and facts received, the Commission recommended that a small experiment be conducted in which a few research institutions receive funds to establish compensation programs with varying features for several years, so as to establish the need for such programs and the feasibility and expense (both in compensation provided and in administrative costs) of them, and to compare the incidence of reported injuries in these institutions with the experience of other institutions at which research subjects are not offered compensation for injuries on a nonfault basis. The proposed policy experiment should also provide information on whether distinctions can be drawn in practice between harm caused by a therapeutic procedure undergoing testing (for which compensation would not be provided) and harm caused by "nonbeneficial" procedures used in such "therapeutic research" solely for scientific reasons (for which compensation might be appropriate).

The Commission elected not to specify the size, scope, or other details of the experiment—matters better left to those at the Department of Health and Human Services who would have responsibility for supervising the experiment. The objectives of the experiment and details about the programs that could be tested are set forth in the Commission's report and its separate appendix volume, which also contains additional supporting material. Briefly, the report addresses the following issues:

(1) *Is there an ethical obligation to compensate injured subjects?* The Commission concluded that there is a moral obligation to compensate subjects for injuries that were caused by research, since research is an activity undertaken to benefit humanity generally and its costs ought not to fall dispropor-

tionately on a few people. Testimony from scientists and research institutions indicated that they generally feel themselves obligated to provide emergency medical care to injured subjects.

(2) *Is the Federal government, as a sponsor of research, obligated to establish a compensation program?* Not necessarily; that depends upon whether injured subjects are not being fairly treated under the present system. To justify a formal program it is necessary to demonstrate the existence of an unmet need and weigh that need against other needs in the public arena, the Commission concluded. The current lack of definitive data on the incidence of injuries makes it premature for Federal research sponsors to require compensation programs at research institutions; the lack of data does not, however, mean that injuries do not occur.

(3) *How can it be established whether a program is needed?* The experiment suggested by the Commission would provide data on the rate and severity of injuries at participating institutions. Comparative data on the injuries at other institutions not providing compensation would be forth-

coming if the Federal agencies that support human research also adopt an earlier recommendation of the Commission—that scientists conducting Federally supported research with human subjects report annually the number of subjects who participated in each experiment and the nature and incidence of serious adverse effects that resulted, if any.

(4) *What other information would the experiment provide?* The experiment should indicate what effects would be expected in formal compensation programs. For example, will the availability of compensation generate an increased number of reported injuries? Will it produce a large number of specious claims? Through the experiment, different techniques for



controlling a program's costs, both in claims paid and in administrative expenses, can be tested. The experiment would be designed to determine whether injuries resulting from a research procedure can be reliably distinguished from any adverse effects of therapeutic interventions or preexisting illness. It may also be possible to discover whether the presence of a compensation program would make it easier for researchers to recruit subjects.

(5) *Who ought to conduct the experiment?* HHS, the major sponsor of human research, should design and administer the compensation experiment with appropriate consultation by other governmental bodies that sponsor or conduct human research.

Response to the Report. Although doubts had previously been raised about the availability of insurance for nonfault compensation for research injuries, the Senior Counsel of the American Insurance Association told the Commission:

We would like to participate in seeing that a reasonable compensation program for human subjects is developed. Insurance companies will risk their assets only after careful study. The opportunity for the companies to experiment with the kinds of coverage which would be necessary is an important ingredient in developing a program which will survive over the long run. Continued study, including the development of pilot programs, would be the best route to develop an actual program for the compensation of human subjects.

Secretary Schweiker published the Commission's report in the *Federal Register* on November 23, 1982 (47 *Federal Register* 52880) and, at the same time, asked the Director of NIH to establish an ad hoc committee to consider how to respond to the Commission's recommendations. That committee is scheduled to begin its work shortly. To assist in this task, the Commission has provided copies of the report and appendix volume for each committee member.

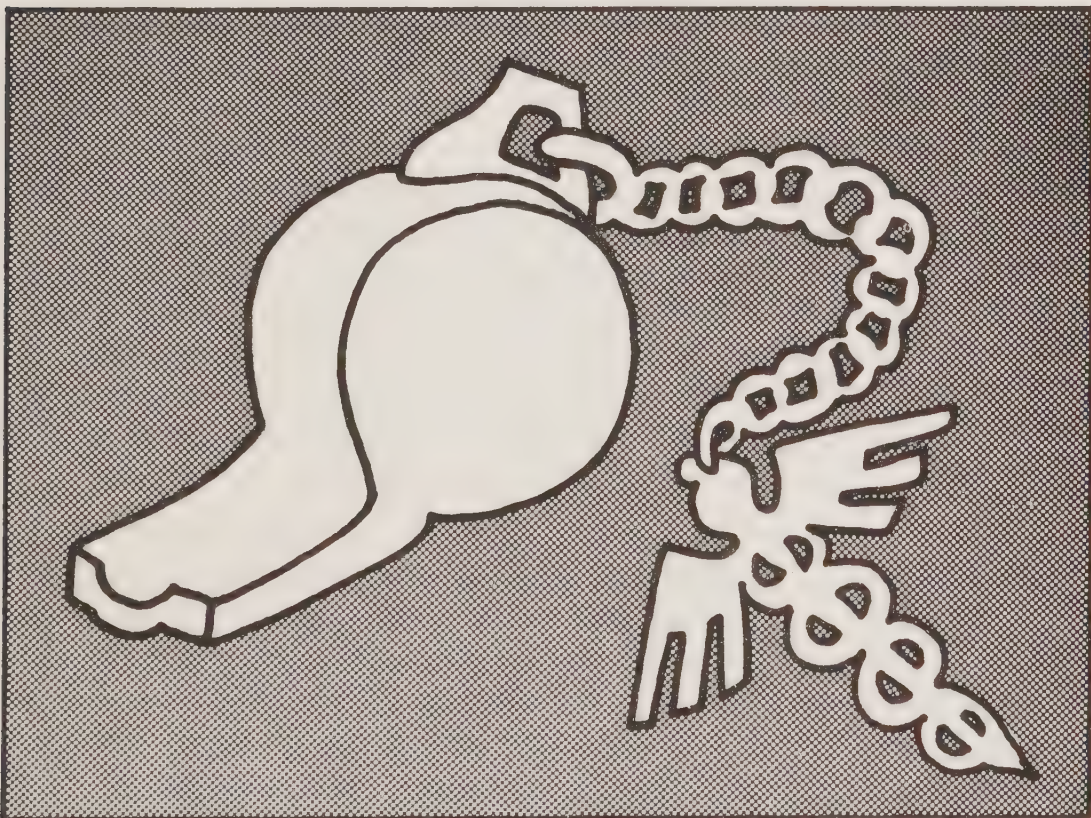
Whistleblowing in Research

Incomplete or inaccurate research data, as well as violations of applicable regulations, may pose serious risks to research subjects. In addition, fraud in research may place future patients at risk if decisions to adopt or abandon a particular therapy are based upon incomplete or inaccurate data. More fundamentally, of course, fraud in research deeply affects the structure and conduct of science. Scientists may waste years of work building on false leads, and the scientific enterprise as a whole may lose the confidence and support of the general public.

Whistleblowing in Biomedical Research, p. i

The Issues. As part of its responsibility to determine the adequacy of the implementation of rules designed to protect human subjects, the Commission reviewed several widely publicized cases of misconduct in the performance of Federally sponsored biomedical research. The Commission was concerned that no standards and procedures exist for alerting review committees about serious allegations against a scientist whose application for further research support is under review, protecting those who report misconduct from retaliation by their institutions or the accused, protecting the rights of the accused by initiating investigations of allegations in a fair and timely manner, protecting the research subjects if allegations are sufficiently serious to warrant suspension of the research activities, and protecting the public interest by assuring the reliability of research results and the ethical conduct of research supported by public monies.

The Commission's Study. As part of its study of these issues, the Commission cosponsored a Workshop on Whistle-blowing in Biomedical Research with the AAAS Committee on Scientific Freedom and Responsibility and with Medicine in the Public Interest. The meeting took place on September 21 and 22, 1981, at the Institute of Medicine in Washington.



Participants included physicians engaged in biomedical research; hospital administrators; professors of law, political science, sociology, and educational administration; practicing attorneys; officials of the National Institutes of Health and the Food and Drug Administration; a member of the President's

Commission, and senior staff of the sponsoring organizations. The purpose was to explore the need for additional procedures to protect “whistleblowers,” the accused, research institutions, the public interest, the scientific enterprise, and human research subjects when incidents of misconduct in biomedical research occur. The ultimate goal was to identify mechanisms to encourage adherence to high standards of conduct in the pursuit of scientific knowledge and to discourage misconduct to the extent possible.

After two days of discussion, participants reached consensus on several major points. Additional issues of concern were identified, with strong minority views regarding possible solutions, but without the full consensus of the group.

The Workshop’s Report. The recommendations that received unanimous support are as follows:

(1) Institutional Review Boards (IRBs) should not be expected to perform monitoring, investigative, or adjudicative functions. Applicable regulations should be clarified as to what is intended (and not intended) by the requirement that IRBs perform “continuing review” and report serious and continuing noncompliance to the funding agency. IRBs do not have the time, the resources (staff or money), or the expertise to perform such functions. In addition, adoption of the monitoring role would conflict with the primary role of IRBs: to educate and advise research scientists and to resolve problems in a constructive way. And many—if not most—institutions already have appropriate quality assurance mechanisms in place, although perhaps an IRB member should sit on such a committee. (A committee clearly exists in the case of hospitals; it may not for the majority of universities.) IRBs should be kept informed of all allegations, investigations, and findings of misconduct in research with human subjects. The IRB might also be consulted as to the seriousness of misconduct found to have occurred.

(2) Institutions receiving Federal research grants and contracts should be required to describe to the funding agency their procedures for responding to reports of misconduct. The procedures should include mechanisms for assuring a prompt investigation; an impartial adjudicator; full opportunity for the complaining parties and the accused to explain their positions, present evidence, call witnesses, etc.; and protection from reprisals for the good-faith complainant and for witnesses.

Information about these procedures should be widely disseminated throughout the institution so that all persons who might be involved in research with human subjects would know what office to contact and what their rights and protections would be. The IRB could also receive reports, and then forward them to a designated office.

In descriptions of the mechanism, institutions should make clear the nature and extent of an IRB's involvement in the process of resolving complaints and in determining whether the findings should be reported to the funding or regulatory agency.

(3) Institutional administrators, principal investigators, and research personnel should be made aware of their responsibilities to the scientific community and to Federal agencies. Education and attitude can play a large part in encouraging adherence to professional norms and standards. Administrators' responsibilities include prompt and appropriate action when misconduct is reported and the establishment of a clear institutional commitment to upholding professional standards and enforcing Federal regulations. Staff can be encouraged to report problems through internal channels by protecting those who report in good faith and by imposing appropriate disciplinary measures for serious acts of misconduct.

Administrators and scientists should understand that they have a legal obligation to report serious misconduct to the appropriate Federal agency, once a formal determination of it has been made. In fact, to knowingly provide false information to the Federal government is a felony. If an institution makes a formal finding that false information has been submitted in a grant application, annual report, or data submitted to a regulatory agency, it may incur criminal liability if officials fail to report the finding.

Professional societies and state licensing boards can also encourage adherence to scientific norms and compliance with Federal regulations governing research with human subjects. Professional codes of ethics should include such principles, and licensing bodies might make training in research standards and ethics a prerequisite for licensure. In addition, misconduct in research could be identified as a basis for disciplinary action by state licensing boards and by professional societies and specialty boards.

(4) Federal agencies should respond in a consistent and fair manner to reports they receive; other Federal agencies, state licensing boards, and appropriate professional societies should be informed of any final determinations of misconduct. NIH and FDA should continue their efforts to clarify standards and procedures for response to reports of misconduct in research under their jurisdiction. They should work together, with a uniform set of standards, on investigations of incidents in which both agencies have a regulatory interest. Procedures to protect both those who are accused and those who make good-faith reports of misconduct should be developed and disseminated to all agency staff who might receive such reports or participate in an investigation. Formal determina-

tions of misconduct should be actively shared with other Federal agencies, state licensing boards, and national organizations such as professional societies and pharmaceutical manufacturing associations, as appropriate. (Currently, such information is available on request, but no attempt is made to forward reports to other agencies or boards unless a specific request is made.)

Response to the Report. The conclusions and recommendations of the Workshop were reported to the Commission and formed the basis of several recommendations in its First Biennial Report, *Protecting Human Subjects*. An edited version of the Workshop proceedings was published in 1982. In addition, the transcript was made available to an Ad Hoc Committee on the Maintenance of High Ethical Standards in the Conduct of Research, appointed by the President of the Association of American Medical Colleges (AAMC) in January 1982. The recommendations of that Committee were adopted by the Executive Council of the AAMC in June 1982 and have been widely disseminated in the form of a pamphlet. Since then, several universities have formally adopted guidelines for the conduct of collaborative research, in which the responsibilities of scientific investigators are set forth and the universities' policies regarding misconduct are explained.

First Biennial Report

Research with human beings plays an essential part in combatting disease and in expanding the frontiers of knowledge....Not only is research essential but it is equally essential that this important human activity be carried out without needless risk or distress and with the willing and enlightened cooperation of its subjects.

Protecting Human Subjects, p. 1

The Issues. The Commission was mandated to report biennially to the President, the Congress, and appropriate Federal agencies on the protection of human subjects of biomedical and behavioral research. Each report was to review the adequacy and uniformity of the rules, policies, guidelines, and regulation of all Federal agencies regarding the protection of human subjects of biomedical or behavioral research that such agencies conduct or support. The reports were also to consider the implementation of such rules, policies, guidelines, and regulations by Federal agencies, and could include recommendations for legislation and administrative action that the Commission deemed appropriate.

The Commission's Study. The topic was on the agenda of 11 Commission meetings, including hearings held in Boston and Los Angeles to examine the policies and procedures of local institutions and of Federal officials for responding to reports of misconduct in Federally supported research. The purpose was

to learn from administrators and IRB members at the research institutions involved, as well as from principal investigators and those who reported misconduct, how well they believe existing procedures worked and what improvements they might recommend. A number of suggestions regarding IRB authority, institutional mechanisms for investigating and adjudicating reports of misconduct, and Federal procedures for monitoring compliance were received and considered by the Commission. The Commission also held a hearing on Federal regulation of behavioral and social science research, paying particular attention to extension of Federal rules to non-Federally funded activities.

In September 1980 the Commission made recommendations to HHS Secretary Harris on the Department's proposed revisions to its rules governing research with human subjects (45 CFR 46). Based upon testimony received at a public hearing and its own consideration of the issues involved, the Commission proposed specific exemptions from prior review for most forms of social science research and some categories of behavioral research that present no risk of physical or psychological harm and no invasion of privacy. The Commission also informed Secretary Harris of its conclusion that the Department currently lacked statutory authority to extend HHS regulations to research conducted at grantee institutions but not supported by Departmental funds. (The Director of the Office of Management and Budget and the Director of the Office of Science and Technology Policy subsequently endorsed the Commission's position.)

A detailed analysis of the rules of each of the Federal agencies involved in research with human subjects was prepared by the Commission staff. The analysis revealed that: (1) most of the Federal entities have formal rules and policies for protecting human subjects; (2) these rules and policies largely conform to the HHS regulations published in January 1981, which were revised in light of the recommendations of the National Commission for the Protection of Human Subjects and which are regarded as the "lead" regulations in the field; and (3) the small differences that do exist are now buried amidst hundreds of pages of rules that unnecessarily repeat the "core" of the HHS regulations, creating confusion, imposing a burden on IRBs and research institutions, and impeding Federal oversight activities.

The second half of the Commission's charge regarding the protection of human subjects was to determine the adequacy and uniformity of the rules' implementation. From questions posed to Federal agencies, as well as from a review of several widely publicized incidents of alleged misconduct in Federally funded research, the Commission found that great diversity exists in the manner in which grantee institutions implement

the regulations, that most funding agencies know little about institutional compliance with the regulations, and that few funding agencies have clear procedures for responding to reports that the regulations may have been violated or that human subjects may have been placed at risk through acts of research fraud or other misconduct.

The Commission's Report. *Protecting Human Subjects*, which was submitted to the President, Congress, and the heads of all relevant departments in December 1981, recommended the following:

(1) All Federal agencies should adopt the regulations of HHS (45 CFR 46).

(2) The Secretary, HHS, should establish an office to coordinate and monitor government-wide implementation of the regulations.

(3) Each Federal agency should apply one set of rules consistently to all its subunits and funding mechanisms.

(4) Principal investigators should be required to submit annual data on the number of subjects in their research and the number and nature of adverse effects. In preparing *Compensating for Research Injuries*, the Commission had been disappointed to discover that no data are collected from which to determine either the number of human subjects involved in Federally supported research in a given year or the nature and incidence of serious injuries associated with such research. Although the Commission recognized the difficulty of developing a definition of "adverse effect" that would be useful in the reporting of significant injuries, it was confident that a definition could be developed over time.

(5) The National Commission's recommendations on research involving children and the mentally disabled should be acted upon promptly. Ethical concerns about these individuals revolve around the issue of informed consent. In order for research on the causes, treatment, and prevention of pediatric diseases and of emotional and cognitive disorders to proceed in an ethically acceptable manner, the National Commission had urged the adoption of special protections for children and the mentally disabled. Although the Secretary, HEW (now HHS), was to respond promptly to that Commission's recommendations, it had been four years since those recommendations had been submitted.

(6) "Private" research organizations receiving direct Federal appropriations should be required to follow regulations for the protection of human subjects.

(7) Institutions should be free to use offices other than IRBs to respond to reports of misconduct and should have procedures for prompt reporting of their findings to the funding agency.

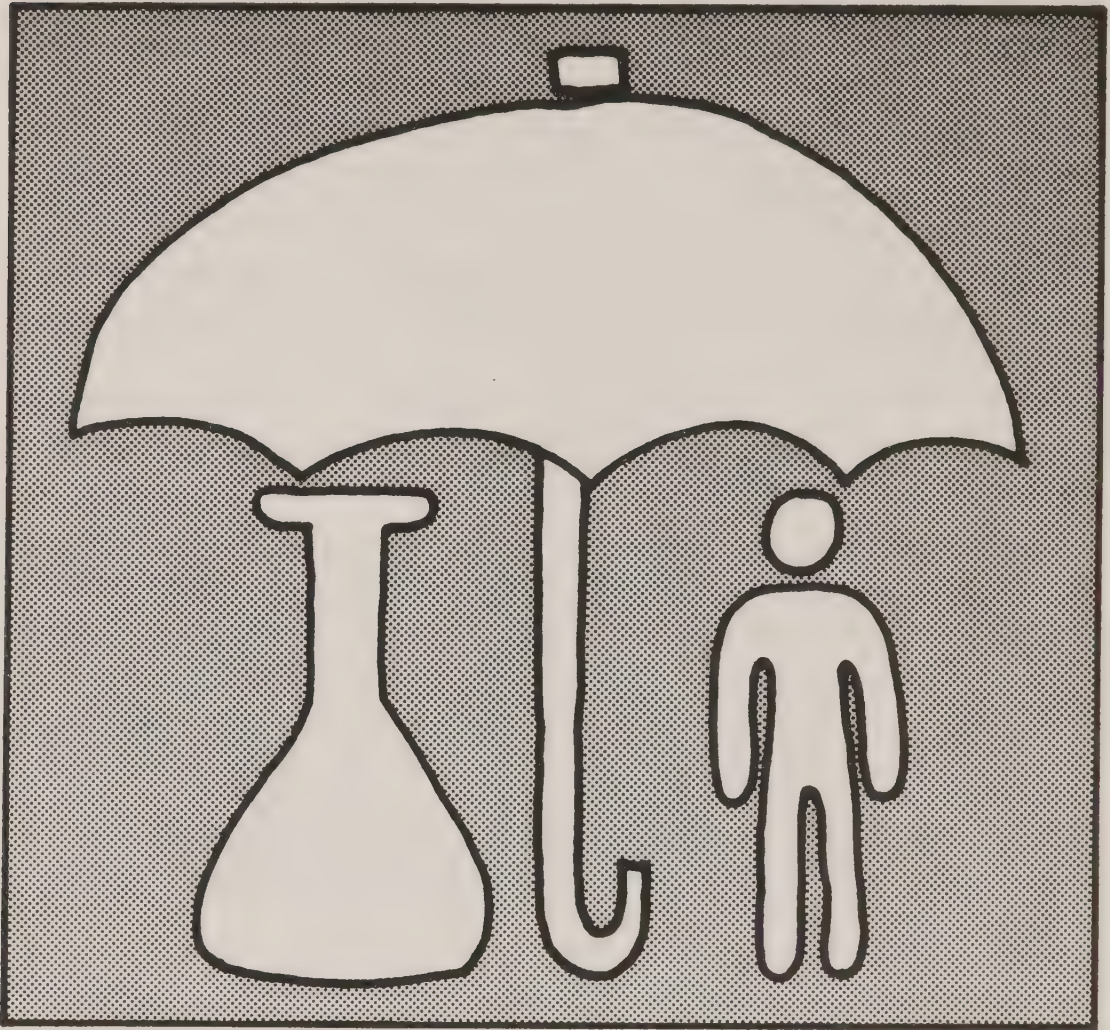
(8) IRBs should be required only to report to appropriate officials of their institution (rather than to the funding agency) when they learn of possible misconduct and to respond to the findings of those officials.

(9) There should be government-wide procedures for debarring grantees and contractors found guilty of serious misconduct, as well as a consolidated list of formal debarments and suspensions that is actively shared with government agencies, professional societies, and licensing boards. Any formal finding by one agency, following such procedures, should be conveyed to other Federal agencies, along with the determination on which it was based.

The recommendation was based upon regulations published in 1981 by the Office of Management and Budget that provide for a uniform standard and consolidated list of individuals barred from receiving Federal contracts. The debarment procedures set forth in the OMB regulations are identical to those of HHS (except that the HHS procedures apply to recipients of grants as well). Thus, the Commission was not recommending extensive new regulations; rather, it was suggesting greater uniformity in the application of existing regulations.

Response to Commission's Recommendations. On January 19, 1981, immediately before leaving office, Secretary Harris wrote to Chairman Abram that she had "approved final recommendations that, for the most part, adopt your recommendations" regarding both limitation of the HHS regulations' applicability to research conducted or supported by the Department and exemptions for certain categories of such research. However, the format in which the Commission had presented the latter point—which grouped the exemptions based upon their rationales, so as to make them easier for IRBs to apply—was not followed in the HHS regulations published in the *Federal Register* on January 26, 1981.

The Commission's basic recommendation in the First Biennial Report that all Federal agencies adopt HHS rules as a central core met with almost universal approval from Federal agencies as well as from scientists and research institutions. Early in 1982, the President's Science Advisor, Dr. George Keyworth, established an interagency Ad Hoc Committee on Protection of Human Subjects to respond to the recommendations of the report. The Committee, chaired by HHS Assistant Secretary for Health Brandt, included representatives of all Federal agencies and departments that support or conduct research with human subjects. Ex officio members included representatives of the Office of Science and Technology Policy, the Office of Management and Budget, the Department of State, and the President's Commission. The Committee had expected



to publish by the end of 1982 a set of guidelines endorsed by all affected agencies, but has, as yet, been unable to do so.

Concerning the Commission's second recommendation, Dr. Brandt indicated at meetings of the Ad Hoc Committee that the Department intended to designate the Office for Protection from Research Risks at NIH as responsible for coordinating government-wide implementation of the uniform set of regulations to be adopted. The Committee has also discussed the recommendation that principal investigators report annually on the number of subjects and the number and nature of adverse effects, although to date the Commission has received no information on this issue.

The Department has partially responded to Recommendation (5) regarding rules to protect children and the mentally disabled who are asked to participate in research. After further encouragement from the Commission during 1982, HHS on March 8, 1983, published in the *Federal Register* regulations for research involving children. Although the Commission has continued to urge HHS to act expeditiously to remove regulatory ambiguities and impediments that may exist to research with mentally disabled subjects under conditions that would assure ethical protection to those subjects, Secretary Schweiker has informed the Commission that no regulations will be issued by HHS research involving persons institutionalized as mentally disabled.

Regarding the report's recommendation that "private" research institutions that are funded by direct Congressional appropriations comply with regulations for the protection of human subjects, the Commission has been informed by its HHS Liaison that the Gorgas Memorial Institute of Tropical and Preventive Medicine, the organization that prompted the recommendation, has since voluntarily entered into negotiations with NIH for an approved assurance of compliance with HHS regulations. Nevertheless, since Congress may from time to time provide research support directly to other organizations, the recommendation that such funds be conditional upon compliance with regulations for the protection of human subjects remains valid.

Two of the recommendations in the First Biennial Report required only clarification of existing regulations regarding the role of IRBs and how they relate to other offices within a research institution. No clarification has been issued as yet by HHS, although the Commission has been informed that the recommendations were accepted in principle by the committee charged with drafting the new government-wide rules for human subjects' protection. Nor has action been taken yet on the Commission's recommended uniform set of procedures for the response of Federal agencies to reports of misconduct by grantees and contractors. The Commission, through its Chairman and senior staff, encouraged and assisted officials at various levels within HHS to clarify Departmental policies and procedures on this subject during 1982. Although an NIH ad hoc committee has drafted a policy, as of February 1983 discussions were still in progress within the Department and no final policy statement had been issued.

Second Biennial Report

When people rely on rules to protect them from harm, they are not interested in pieces of paper but in the conduct of the people who are supposed to be governed by the rules. Having looked for the most part at the adequacy of the rules in its first biennial report on the protection of human subjects in research, the Commission turns in this second report primarily to the question of the rules' implementation.

Implementing Human Research Regulations, p. 1

The Issues. The primary focus of *Implementing Human Research Regulations*, the Commission's Second Biennial Report, was the development of better procedures for monitoring the performance of Institutional Review Boards. Yet the Commission also identified several topics, which it had not had the time or resources to study, that should be considered as soon as practicable by a government-wide coordinating group,

an Ethics Advisory Board within HHS, or other appropriate body:

- Should Congress give Federal agencies the authority to extend their regulations to non-Federally funded research?
- What is the relationship, and what should it be, between IRBs and scientific review groups (study sections), which are now required by NIH to consider ethical as well as scientific issues?
- Should IRBs review certain types of research with brain-dead individuals and with cadavers to ensure the procedures are consistent with commonly held convictions about respect for dead?
- In the case of experimental anti-cancer drugs, does the description of Phase 1 drug testing (the first introduction into human beings) as always “therapeutic” mislead cancer patients about the likelihood of any therapeutic benefit of their participation in the research?
- What will be the various effects of a proposed revision of FDA regulations to permit approval of new drugs based solely on data from clinical trials conducted outside the United States?
- Can unethical research best be discouraged by the refusal of scientific journals to publish the results or by the publication of such questionable results along with critical editorial commentary?
- What should the role of nonscientific and unaffiliated members of IRBs be?

In considering better ways to monitor IRB performance, the Commission noted that very little is known about the actual functioning of these boards or about research institutions’ compliance with HHS regulations for the protection of human subjects. Although the Commission’s predecessor, the National Commission for the Protection of Human Subjects, had proposed in 1978 that HHS establish procedures for conducting site visits to IRBs, the recommendation had never been implemented by HHS. The President’s Commission therefore undertook a pilot study to explore whether site visits by peers from other institutions—people who are familiar with IRBs—would improve Federal agencies’ ability to know whether their rules are being well implemented.

The Commission’s Study. Site visits to 12 IRBs were conducted under the direction of a special consultant to the Commission. Based upon these reviews, the site visit teams prepared a critique of their experience, including suggestions for modifications of this approach for subsequent site visits. The “protocol” of the site visit thus evolved over the course of

the trial. The consultant who directed the study, and four of the site visitors, presented their findings and conclusions to the Commissioners at a meeting in September 1982. The Commissioners then received comments on the results of the study from the HHS Liaison to the Commission, the FDA Associate Commissioner for Health Affairs, and a representative from the Association of American Medical Colleges.

The Commission's Report. The Commission favors a uniform system of assuring implementation of the regulations through prior assurances and periodic site visits. Several departments and agencies now conduct inspections of IRBs to assess regulatory compliance, and some others apparently plan to do so. Other agencies rely on the supposed adequacy of the process used by HHS to administer its human subjects regulations, which does not now routinely include site visits to IRBs. Based upon the findings of its study, and on the criticisms and concerns of those who commented on it, the Commission recommended that there be a uniform system of ensuring implementation of the regulations through prior assurances and periodic site visits.

A combined approach, which includes both a prospective assurance mechanism and retrospective site visits, will permit Federal agencies to know that the IRBs that are actively reviewing research are properly constituted and procedurally sound and that they are functioning properly.

The composition of an IRB should be examined to determine both whether it satisfies regulatory requirements and whether it is adequate in light of the types of research to be reviewed. In addition, IRB procedures for reviewing protocols should describe such things as what information is submitted for review by investigators, what information is distributed to all IRB members, what review activities take place prior to or outside of IRB meetings, and what procedures are used to notify investigators about needed changes.

Site visits to IRBs should be part of agencies' education and monitoring efforts. Among educational techniques for those responsible for the protection of human subjects, the Commission found the kind of site visits performed in its pilot study to be particularly helpful and effective. Although it was based on a small number of IRBs, the Commission's project suggested that there is great variability among IRBs in their review procedures and room for improvement in the way some IRBs function.

The functioning of an IRB can best be evaluated by people knowledgeable about and experienced with the work of IRBs, given the difficult judgments IRBs must make and the complex relationship between IRB performance and its composition and procedures. Suggestions for improvements seem most likely to

be accepted by an IRB if they are made by site visitors who are regarded as peers (that is, experienced IRB members or staff).

All agencies, particularly NIH and FDA, should consider budgeting funds already available for education and compliance activities to the conduct of more site visits. Cost, administrative efficiency, regulatory needs, and public accountability should all be considered in developing a site visit program.

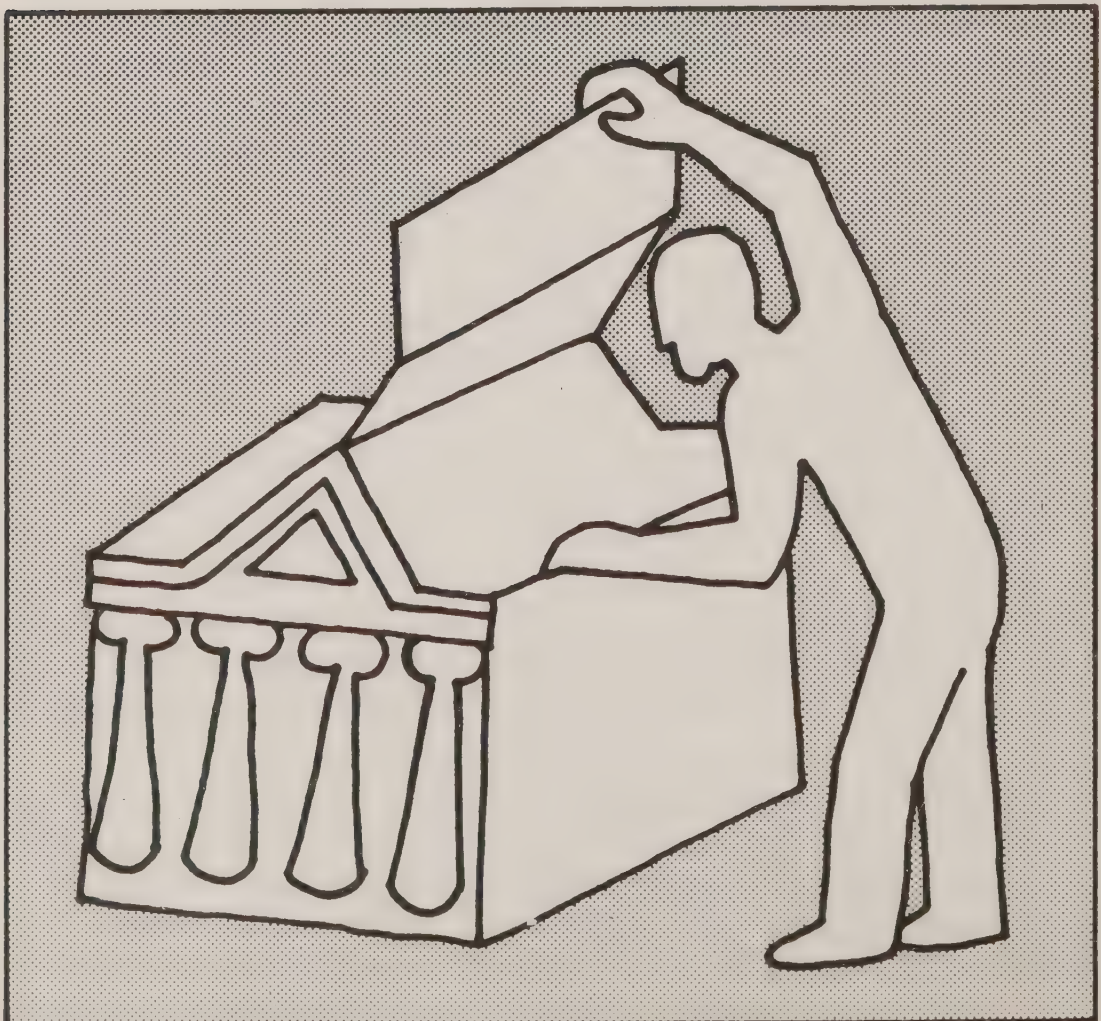
In determining the kind of program to adopt, the Commission urged agencies to consider the following lessons of its site visit project:

Useful information can be derived from interviews with IRB members, IRB staff, and investigators, from a review of records, and especially from attendance at IRB meetings.

An excessive emphasis on regulatory conformity reduces the value of site visits as an educational tool and makes it more difficult to recruit suitable site visitors from outside government.

Site visits of one day provide visitors with a firm basis for identifying problems and offering suggestions; in some instances, a day and a half may be preferable.

In addition to preparing the Second Biennial Report the Commission, through its Chairman, corresponded with HHS



Secretary Schweiker in early 1982 concerning the Department's proposal to exempt certain social policy experiments from the requirements of 45 CFR 46 for IRB review and informed consent. Programs for which social policy experiments would be exempt from IRB review under the HHS proposal include Medicare, Medicaid, Aid to Families with Dependent Children, Head Start, Developmental Disabilities, Child Abuse Prevention and Treatment, the Native Americans Program, and the Social Security Disability Amendments of 1980. The HHS proposal to exempt all such research from IRB review (47 *Federal Register* 12276, March 22, 1982) met with sharp criticism from a number of public interest groups including the Leadership Conference on Civil Rights, the Childrens Defense Fund, and the Gray Panthers.

The Commission urged that IRB review be required for any social experimentation involving the restriction or limitation of benefits to which the subjects would otherwise be entitled by law (and which would continue to be provided to individuals not involved in the research). This would assure that the risks of the research are justified by the benefits anticipated, and that the research is well-designed and thus the knowledge sought is likely to be obtained. On March 4, 1983, the Department announced that it was adopting the proposed exemption, with minor modifications (48 *Federal Register* 9266-70).

IRB Guidebook

It is neither possible nor necessary to draw a clean line between biomedical and behavioral research. Some biomedical research pertains to behavior...and many of the methods used in behavioral research, such as observation and the questioning of subjects, are also used in biomedical research....The questions that are of concern to IRBs stem not from the label attached to the research but from the nature of the interventions and the characteristics of subjects in any given study. It is for this reason that institutions and Federal agencies are concerned that IRB members be knowledgeable about the broad types of research reviewed by that IRB.

The Official IRB Guidebook, pp. 4/A1-2

The Issues. As the series of IRB hearings held by the National Commission for the Protection of Human Subjects made clear, IRBs both need and want additional guidance on fulfilling their responsibilities. HHS has been planning to develop commentaries on the regulations as part of its education program following the issuance of amended regulations in January 1981. On the advice of a group of consultants convened in the fall of 1980, the President's Commission decided to collaborate with NIH's Office for Protection from

Research Risks, and with the Food and Drug Administration, to develop a guidebook for IRBs that would go beyond an explanation of the regulations to explore varying positions taken by commentators and to suggest points to consider in IRB review.

The Development of the Guidebook. Initial contributions for portions of the guidebook were developed under a contract with Public Responsibility in Medicine and Research (PRIM&R), a Boston-based nonprofit organization that sponsors conferences on topics related to the protection of human subjects and that publishes educational materials of general interest to IRBs. The guidebook drafts were reviewed by an editorial board comprised of several members and senior staff of the Commission, NIH and FDA officials, research scientists, and IRB members and administrators from outside the Federal government. The Office for Protection from Research Risks (OPRR), in collaboration with the Office of the Associate Commissioner for Health Affairs at FDA, developed commentaries on their regulations. Copies of the Guidebook will be mailed in Spring 1983 to all IRBs with approved assurances on file at NIH, IRBs regulated by FDA, and members of the Pharmaceutical Manufacturers Association. Additional copies will be available from OPRR.

The Contents of the Guidebook. The Guidebook, which is published in a loose-leaf binder to permit additions and revisions over time, covers:

Background—provides a useful introduction for new IRB members and for investigators just beginning their clinical research.

Regulations and Commentary—will help resolve uncertainties about the intent or interpretation of regulatory provisions and will be a useful reference for initial reviewers of research proposals.

Administration of an IRB—is directed primarily at institutional administrators and IRB Chairs but will also be of interest to clinical investigators and research sponsors and to lay members and others concerned about how the IRB relates to other institutional offices; includes a list of suggested materials for an IRB library.

Research Goals and Procedures—describes research subject matter, goals, and methods in a general, introductory way and provides references for further reading; will be of most benefit to nonscientists on the IRB and to scientist-reviewers considering a research proposal in a discipline with which they are unfamiliar.

Considerations of Research Design—describes the reasons for using certain experimental designs and ethical issues that can be raised by such use.

Basic IRB Review—in discussing how regulations might be applied in various situations, presents the major focal points of IRB review: informed consent, risk/benefit analysis, privacy and confidentiality, selection of subjects, and incentives for participation.

Special Classes of Subjects—looks at ethical issues in research involving classes of particularly vulnerable research subjects (such as children and prisoners).

Forms—provides sample HHS forms, consent forms, forms for principal investigators' submission for IRB review, etc.

Local IRB Organizational Documents—gives each institution and its IRB a place to insert their own documents.

Glossary—explains terms used in reviewing biomedical and behavioral research; useful for lay members as well as scientists who need clarification of terms in disciplines they are not familiar with.

Recurrent Themes

4

The Commission was asked by Congress to study a number of topics in medicine and research that have aroused widespread feelings of disquiet. Although the topics were diverse, all involved the important issues of “bioethics” in one form or another. This field involves much more than the study of moral philosophy. In the Commission’s deliberations, social, legal, economic, and religious concerns, as well as those traditionally regarded as “ethical,” were all components of “bioethics.” Having chosen to address this field not through a single, consolidated document but by producing a small library of reports, the Commission had many opportunities to examine from different angles the perplexing problems that arise at the intersection of medicine and research with public policy and personal and professional values.

Sometimes the difficult issues were conceptual in nature—for example, how to “define” when death occurs. More often the difficult issues were due to conflicts involving competing values and/or interested parties.¹ The possible permutations of parties and values are virtually endless. Some problems require balancing competing values for a single individual—such as individual autonomy against individual well-being. At other times, a choice must be made between the competing interests of two or more individuals, or of two or more types of parties—examples include the health of an individual patient

¹ The values and goods found to come into conflict with one another in the various areas addressed by the Commission include: health, privacy, autonomy, knowledge, and economy. The parties include: individuals (competent and incompetent, patients and research subjects), families, health care professionals (including researchers), health care and research institutions, third-party payors (insurance companies, Federal assistance programs), government agencies, and society as a whole.

versus that of other patients needing the same scarce medical resource, and the well-being of an individual patient contrasted with that of others in the patient's family when, for example, spending money for care would exhaust the family's financial resources. Although in some cases it may be clear whose interests and which values should predominate, the Commission found that most of the fields it studied are characterized by countless "hard cases." In medicine and research—as elsewhere—hard choices arise when there is no general rule that is clearly applicable and correct in all cases.

When substantive rules seemed inadequate to govern particular situations, the Commission attempted to identify the various factors that lead to ethically defensible decisions and to suggest procedures that would make the careful consideration of those factors more likely. Thus, the Commission's attention was frequently directed toward the process of decisionmaking rather than toward a specific proper outcome. At times, the Commission recommended a framework that included both a process and guidelines for applying it, with outer limits for acceptable results.

Ethical Principles

The Commission appealed to a number of ethical principles in its studies. Both in the earlier reports and in this final volume, these principles are not identified for a reductionist purpose: by themselves they are not rich or variegated enough to express the complexity of the situations and issues the Commission examined. Medicine and research touch too many of the central facets of human existence—natality and mortality, knowledge and opportunity, comfort and pain, ancestry and progeny—to be summed up in a few principles.

Nonetheless, analysis proceeds by simplification and generalization. In the Commission's analysis, three basic principles predominated:

- that the well-being of people be promoted,
- that people's value preferences and choices be respected, and
- that people be treated equitably.

The Commission has not undertaken to rank these three principles among themselves nor to set them above other values—such as efficiency and honesty—that were less prominent in the particular studies it conducted. Although it has tried to apply these principles consistently in its various reports, the Commission has made no attempt to develop a comprehensive theory of bioethics: its assignment from Congress was not to develop theories but, more practically, to consider the implications of particular practices and developments in the life sciences.

These principles—though they do not summarize the whole American ethos—are a basic part of the Western cultural and philosophical traditions. Earlier bioethical studies have shown, in varying ways and with differing emphases, the principles' special importance in evaluating the ethical implications of decisions, actions, and policies in medicine and biomedical and behavioral research.²

Well-Being. In a biomedical context, the obligation to promote well-being has two major manifestations. First, regarding individuals, it has both negative and positive meanings. The former, as expressed in the words of the Hippocratic oath—"do no harm" to the patient—is usually understood to mean that great care must always be exercised and each step be carefully weighed. The latter means that all interventions should be calculated to improve the individual's health and welfare generally as he or she conceives it. The principle of well-being also commands that the interests of incompetent patients be protected, according to the standards that a reasonable person would apply under the circumstances in weighing potential benefits and risks. Second, the principle of well-being also means that consideration should be given to the welfare of others besides a particular patient. In addition to the other immediate participants in health care (such as the patient's family, physicians, nurses, and so forth), there are also the members of the larger community, including future patients who may benefit from the knowledge that is gained from the way a medical intervention is performed today. In caring for a patient, a physician is exhibiting the value of doing good for others—but the implementation of the value may necessitate a broader perspective if medicine as a whole is "do good" for humankind.

The Commission accepted the emphasis traditionally placed on the first part of the principle: 'promotion of patient well-being provides the primary warrant for health care.'³ But an understanding of the second half of the principle—and its relationship to the first—is of increasing importance, for reasons explored later in this chapter. Whether the issue involves protecting relatives from undue psychological strain during a patient's dying days or hours, adjusting the way health care is provided to reinforce professionals' ability to perform their functions, or designing a research project to test a

² See, e.g., National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *THE BELMONT REPORT*, U.S. Department of Health, Education, and Welfare, Washington (1978) at 4-10; Tom L. Beauchamp and James F. Childress, *PRINCIPLES OF BIOMEDICAL ETHICS*, Oxford Univ. Press, Oxford (1979).

³ President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *MAKING HEALTH CARE DECISIONS*, U.S. Government Printing Office, Washington (1982) at 44.

new method of treatment against an accepted one, promoting well-being does not mean adopting a course that involves no risk of harm for anyone (an impossible task—or one that invites paralysis). It means deciding when certain risks to particular persons are justifiable in light of the benefits to those individuals and to others.

Respect. Showing respect for people in health care situations has several important aspects: that patients be given information about the possible courses of action and that their choices about health care be honored whenever possible, that the legitimate expectations of privacy be safeguarded (that is, that individuals retain control over use of private information about them), and that health care professionals not be required to act contrary to their consciences or their values.

The first two of these obligations are probably the most familiar. They are commonly phrased as the principle of self-determination: “that individuals should be treated as autonomous agents, and...that persons with diminished autonomy are entitled to protection.”⁴ To differentiate this aspect of respect for persons from the other, the Commission makes special reference to the self-determination principle—although the rationale for honoring self-determination also supports other aspects of the principle of respect for persons.

Self-determination is “valued for the freedom from outside control it is intended to provide” and “manifests the value that Western culture places on each person having the freedom to be a creator—‘a subject, not an object.’”⁵ But the emphasis on “self” (or on “autonomy”) is not meant to suggest that patients ought to—much less that they do—make their decisions in isolation from the significant people in their lives, including the health professionals who are caring for them, as well as their families and friends. Nor should the word “determination” be taken to imply an overly rational process of decisionmaking. The medical conditions that entered into the Commission’s studies—genetic diseases, life-threatening illnesses, and so forth—provided vivid reminders that biomedical treatment and research are matters not of abstract philosophy but of very important, strongly felt, and often emotionally perceived concern for those involved.

Balancing well-being and self-determination. Sometimes an individual’s choice may be one that appears unlikely to promote his or her well-being. When these two values come into apparent conflict, a common conclusion is that the individual is incompetent since he or she has made a decision

⁴ BELMONT REPORT, *supra* note 2, at 4.

⁵ MAKING HEALTH CARE DECISIONS, *supra* note 3, at 45-46, quoting Isaiah Berlin, *Two Concepts of Liberty*, in *FOUR ESSAYS ON LIBERTY*, Clarendon Press, Oxford (1969) at 118.

that is “wrong” in the eyes of those who are thought to have the professional competence to judge what is objectively “best” for the person. The Commission, however, took the position that there should be a strong presumption that patients have—or, through an appropriate “informed consent” process, can be enabled to have—the capacity to make decisions about their own health care. The fact that a person’s choice is not one that the majority of others would make if they were similarly situated—much less that it is not consistent with “good medical judgment”—is insufficient ground to disqualify the person from making, and acting upon, the decision in question. It may, however, trigger an inquiry into the patient’s capacity to promote his or her own well-being (as the patient would define it) under the circumstances.

As a result of such inquiries, some people will be found to be unable to exercise self-determination; in these cases, the principle of well-being plays the greater role. Furthermore, some people (for example, young children and the severely emotionally or intellectually disabled) are plainly incapable of making self-protective decisions about some or all matters. In these cases, decisions must be made by others based upon a judgment of what the person would have chosen if he or she were able to do so or, when that is not clear, what would be most likely to promote the incapacitated person’s well-being. As reasonable as this proposition may seem, it often creates tensions in practical policies, so great is the value of individualism in American society.

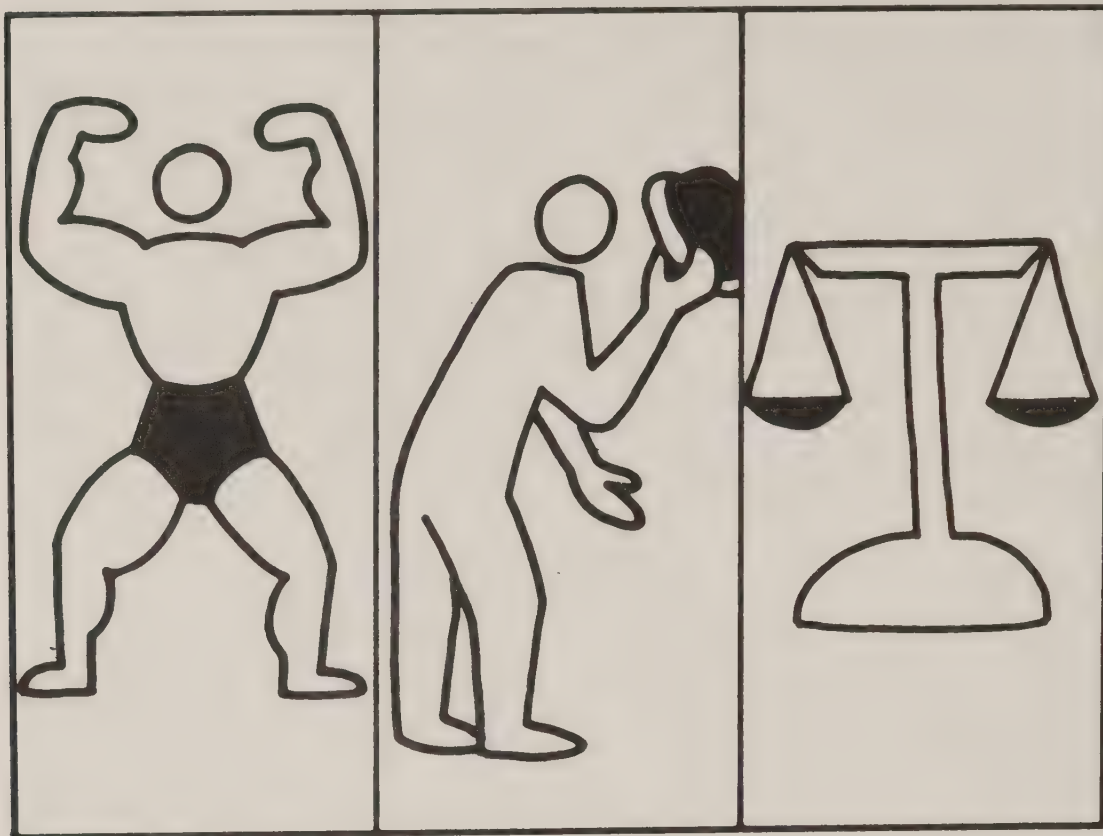
The interests of competing parties. Many interesting restraints on autonomous choices arise out of considerations of others. In a number of its reports, the Commission confronted the question of whether, and under what circumstances, considerations of others may limit individual choice. For example, in *Making Health Care Decisions*, the Commission concluded that patients may be denied treatment options when those options violate the bounds of acceptable practice or a professional’s own moral beliefs or when they would draw on a limited resource on which the patient has no binding claim.⁶

Adjusting the balance between the respect due individual autonomy and the well-being of others arises in a particularly sensitive fashion in genetic screening and counseling. The Commission concluded that it was ethically acceptable to override an individual’s interest in privacy and to release genetic-related information about that person to relatives (or their physicians) if, as discussed earlier, four conditions are met.⁷

In some cases, an apparent conflict between individual choice and the interests of others can be avoided by reexamin-

⁶ MAKING HEALTH CARE DECISIONS, *supra* note 3, at 3, 47.

⁷ See the discussion in Chapter Two *infra*, regarding President’s Commission for the Study of Ethical Problems in Medicine and



ing the actual wishes or needs on each side. For example, in the context of “defining” death, the question would arise were the family of a patient who has been declared dead according to the brain-based standard in the Commission’s proposed statute to insist upon artificially maintaining heartbeat and breathing in the body. The Commission concluded that determinations of whether or not a person is dead must be based on uniform standards and cannot be left to personal discretion. Nonetheless, with the concurrence of a health care provider, room exists for “reasonable accommodation of personal beliefs regarding the actions to be taken once a determination of death has been made,”⁸ although discontinuing medical measures on brain-dead bodies does not in itself violate any ethical requirements.

Equity. The third basic principle—that people be treated equitably—is a matter of central concern in the American tradition, albeit one that raises many practical and philosophical difficulties. Like the other two has several facets. One traditional formulation is the Aristotelian principle of formal justice—that like cases be treated alike. This aspect of the principle certainly has application in the areas explored by the

Biomedical and Behavioral Research, SCREENING AND COUNSELING FOR GENETIC CONDITIONS, U.S. Government Printing Office, Washington (1983).

⁸ President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, DEFINING DEATH, U.S. Government Printing Office, Washington (1981) at 81.

Commission. For example, the conclusion that uniform standards to determine death ought to apply (between persons, over time, across jurisdictions, and so forth) reflects the sense that society would find it unsettling, to say the least, if such an important question were treated as a matter for capricious or unfounded variation among people. Cases in which persons who are alike in relevant ways are treated differently are by definition examples of arbitrariness.

Although there are thus good reasons for holding that the obligation of equitable treatment requires that the dictates of formal justice be followed, the principle has another meaning that is at once broader and less precise. In distributing certain biomedical goods and services, the principle of equity does not mean that all people must be treated alike but rather that all people must be treated fairly. Frequently, it would be unfair to treat everyone identically, that is, to give them the same amount of a thing, since their needs differ or since a proposed course of action affects at most a small subset of the population.

For example, in reviewing research proposals, institutional review boards are enjoined to make sure that the selection of subjects is equitable. This instruction may mean several things: (1) that within any project the process of enrolling subjects will draw evenly from all those who legitimately might be included, or (2) that among all the projects conducted at an institution over a period of time no single subgroup in the population be exposed to a disproportionate amount of risk or burden. Yet the injunction to IRBs cannot, however, mean that a research project on a particular disease must enroll everyone who suffers from the disease so as not to violate the principle of treating like cases alike. Rather, the method of selection must be one that is fair in the sense of being evenhanded and nondiscriminatory.

Recurring Themes and Perplexities

The Commission's mandate to consider ethical issues in medicine and research came at a particularly difficult time in American society. Today, the goals of both enterprises are being reevaluated in light of new capabilities and new constraints. Members of the public sometimes perceive themselves as disenfranchised—excluded from decisionmaking—because of the highly technical and dramatic nature of advances in these fields. Conversely, scientists sometimes face public overreaction to a project based upon misunderstandings of the possibilities and limitations of new technologies.

Although the Commission found certain ethical principles interwoven throughout its studies, the parties involved and the interests at stake varied so that it was never possible to reach conclusions simply by following handy formulas. No matter

how carefully one issue has been resolved, the solution developed cannot be applied in a cookbook fashion to another problem. Rather, each issue—those explored by the Commission and the many awaiting study by its successors—must be examined in the context of its particular circumstances.

Countless complexities inhere in trying to apply ethical principles to decisions in the real world. Nevertheless, several stood out in the Commission's work and amounted more or less to recurring themes: that limited resources impose severe constraints on the pursuit of other values and raise issues of the equitable distribution of those resources, that a tension arises between the desire to rely on experts and the many forms of uncertainty that characterize science and medicine, and that policymakers have a tendency to vacillate between preferring public and private settings for decisionmaking.

Limited Resources. As has already been noted, the principles of serving well-being and promoting self-determination sometimes point in conflicting directions. Yet in the normal course of treatment and research, pursuing them in tandem tends toward the achievement of people's health as they define it. The capabilities of the biomedical sciences both to prevent and to cure illness have expanded immensely in the past half-century; today, health care can offer dramatic remedies for previously untreatable conditions. Nonetheless, an important factor confounds the pursuit of the goal of good health to the full extent indicated by the well-being and self-determination principles: the inescapable reality of limited resources. As the capabilities of health care have expanded, the strain placed on already strapped personal budgets, employer-provided health benefit programs, and the treasuries of governments at all levels—from local to Federal—has become a matter of increasing concern.

The reality of restricted resources means patients, health care professionals and institutions, and society at large must face an ethical problem: having to choose the uses to which limited—in some cases, very scarce—resources will be put. The choices require comparing health care expenditures with other areas of public and private spending, as well as with choices within the health care budget—between treatment and research; between restorative steps for those already ill and preventive steps for those who may be at risk; among different age-groups, diseases, treatment settings, and so forth.

The ethical dilemmas created by the competition for limited resources were vividly displayed in the late 1960s by the efforts to save the lives of patients with kidney failure. Two treatments were available. First, if a donor could be found, a patient's diseased kidneys could be replaced by a healthy kidney. Transplantation offered a "cure" when it was successful, but the supply of kidneys was inadequate and even when

transplantation occurred in most cases it did not succeed because of organ rejection, infection, or the failure of the new kidney for some other reason. Alternatively, patients could undergo hemodialysis two or three times a week, during which their blood was run through a machine for six to eight hours to cleanse it of impurities. While improvements were constantly being sought in both forms of treatment, dialysis was regarded as a proven and reliable (albeit arduous and expensive) method for saving the lives of people who were often otherwise healthy and who, if treated, could look forward to an indefinite continuation of a nearly "normal" life.

Since there were many more people with end-stage renal disease than the dialysis facilities could accommodate, various methods were adopted to select the patients who would be treated. The tragedy of the situation received extensive coverage in the media, including articles about groups like the "God Committee" in Seattle, ordinary citizens who had to decide who in their community most deserved this life-saving resource. At other hospitals, dialysis was allocated on a first-come-first-served basis or according to patients' ability to pay.⁹

By the early 1970s—as the number of people treated moved beyond the small percentage it had been during the early, experimental stages to a greater (though still fractional) portion of the total need—the contrasting fates of those treated and the larger number who died untreated—became intolerable. Rather than continue to seek methods of allocating the resource fairly, a decision was made to make it available to every American with end-stage renal disease under a special provision in the Medicare program.

This response to the dilemma of limited resources is understandable. Indeed, it may have been inevitable, given the drama of identifiable patients who died because they could not obtain life-saving medical treatment. Moreover, the cost of overcoming the tragedy seemed acceptable—in part because of the way in which the number of "eligible" patients was estimated. Over the past decade, however, expenditures on the End Stage Renal Dialysis Program (now totaling approximately \$2 billion per year) have exceeded the original estimates manyfold and the standards for eligibility for dialysis, no longer constrained by a scarcity of resources, have expanded to include many patients whose age or concurrent diseases would have left them out of the calculations of the relevant "pool" of patients in 1972.¹⁰

⁹ Jay Katz and A. M. Capron, *CATASTROPHIC DISEASES: WHO DECIDES WHAT?*, Russell Sage Foundation, New York (1975) at 184-96.

¹⁰ This serves as another reminder of the interaction of "facts" and "values"—in this case, the understandable (and probably unconscious) tendency of physicians to exclude from eligibility for dialysis those patients whose characteristics made their prognosis least

Dramatic, “big ticket” treatments like kidney dialysis and transplantation—or the implantation of an artificial heart at the University of Utah Medical Center in late 1982—are not yet the major strains on the health care budget, but they do crystallize the ethical issues posed by limitations on society’s resources. The Commission concluded that these issues cannot be avoided by the sort of response—“give everyone all they need”—that was used for kidney failure. Instead, the Commission turned to the ethical principle of equity. This principle is always a hard one to know how to apply—as can be seen in the role it played in several Commission reports.

It received greatest attention in the report on the ethical and legal implications of differences in people’s access to health care. On the one hand, the Commission concluded that the importance of health care—in promoting well-being, preventing death and disability, relieving pain, restoring functioning, and generally ensuring opportunity—and the uneven and largely undeserved incidence of illness generated an ethical obligation of society in this area that does not necessarily exist regarding other things. Yet the principle of equity does not create a “right” to health care equal to all the care that some people may obtain for themselves, nor even all that people may want or need, in the sense of its being of some benefit. Rather, equity requires that people have access to an adequate level of care and that the costs of care be fairly distributed. As is always the case in dealing with general principles, such as equity, many of the hardest questions—such as “what level of care is adequate?” and “what constitutes fair distribution?”—remain to be resolved in the context of particular decisions. Instead of searching for a definitive interpretation of the concepts, the Commission attempted to set forth terms of reference by which those who are responsible for formulating policy on health care could compare the ethical implications of alternative proposals.

The need for a principle—besides those of well-being and self-determination—to guide decisions was apparent in other Commission studies as well as in the report on access to health care. For example, in its report on decisions to forego treatment,

favorable. Unlike choices between patients based on such social factors as wealth, education, marital and parental status, and the like, the criteria of “medical suitability” were regarded as “objective.” With sufficient resources, it proved possible to redefine “suitability” since the patients with less favorable prognoses were no longer competing with those who “deserved” the treatment more because their prognoses were better. Though few would argue with a decision to use scarce resources for those most likely to benefit from them, any decision based on people’s deserts is plainly one that involves values, not merely objective facts.

the Commission considered the implications of the equity principle in the context of competition for scarce life-saving resources. When space in an intensive care unit is needed to save the life of a new patient, hospital personnel have to choose either not to treat the new patient or to discharge a patient already in the unit to a less intensive setting. In the case of patients who are carefully diagnosed as permanently unconscious, the Commission concluded that their interest in continued treatment (as derived from the principle of well-being) was so attenuated that an equitable allocation of resources would allow those expended on such patients to be transferred to others who have a better prospect of recovery.



Efforts to identify who has a claim on limited resources can sometimes come into conflict with goals of enhancing personal autonomy. The Commission found such a conflict could occur, for example, if efforts to reduce the societal cost of genetic disease were to lead to calls for mandatory genetic screening (so as to minimize the number of needy individuals) or to the withholding of resources from victims of diseases that genetic screening and counseling might have prevented. Even in the absence of mandatory screening—which comes into direct conflict with self-determination—a societal attitude that would regard people with such diseases (or their parents) as blameworthy or somehow responsible for the condition would exert a subtle but significant pressure on a person's autonomous choice. Thus efforts to decide who gets limited resources might reflect this tension between societal goals of reducing the impact and incidence of genetic disease and the value of screening as a source of information that individuals can avail themselves of as a matter of autonomous choice.

Finally, the difficulties posed by scarce resources may be made even more perplexing by some developments reviewed by the Commission's study of genetic engineering, *Splicing Life*. Society often finds merit a fair means of distributing certain things of value (for instance, admission to selective educational institutions). If in time it becomes feasible to "enhance" various human characteristics and abilities, competition for such treatment will probably be intense, since (at least at first) it is likely to be a scarce resource requiring the

knowledge of highly trained specialists. In such a circumstance,

What sort of distribution would count as fair when the very thing that is being distributed (such as cognitive ability) is itself often the basis for distributing other things of value in society?¹¹

New science can thus make old issues current and, occasionally, even more perplexing.

Uncertainty and Expertise. Difficult bioethical decisions are frequently made even more complex by the background of uncertainty that conditions these dilemmas. In the words of Lewis Thomas:

A solid piece of scientific truth...is that we are profoundly ignorant about nature....It is this sudden confrontation with the depth and scope of ignorance that represents the most significant contribution of twentieth Century science....Because of this, these are hard times for the human intellect.¹²

This inescapable fact takes on special importance because of its effects on another theme the Commission found in its studies, namely the degree to which people, individually and collectively, turn to "experts" for guidance or even for decisions.

The role of uncertainty has pervaded much of the Commission's work. The report on *Making Health Care Decisions* described the variety of sources of uncertainty facing decision-makers. At base, uncertainty affects any proposition about as-yet-unobserved cases. No matter how extensive the past evidence is for an empirical generalization, it may be proven false by subsequent experience. This is the "empirical uncertainty" associated with any knowledge obtained through the scientific method. These limitations on understanding remain even as biomedical research continues to push back the frontiers of knowledge, for that process always reveals more uncharted territory.

Other sources of uncertainty are less cosmic—for example, the limitations inherent in the knowledge of a particular health care provider, since no single person can command the full range of medical knowledge. In addition there is the probabilistic nature of medical decisionmaking—for example, most treatment recommendations are based on a health care provider's view of what is most likely to occur with certain interventions rather than certainty of a particular outcome.

¹¹ President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *SPLICING LIFE*, U.S. Government Printing Office, Washington (1982) at 67.

¹² Lewis Thomas, *THE MEDUSA AND THE SNAIL*, Viking, New York (1979) at 73-74.

This is particularly important in the consent process for treatment and research, since patients and subjects may not be comfortable with probability reasoning—indeed, as the Commission heard during hearings on genetic counseling, it is common for patients to misinterpret health professionals' statements because of their lack of familiarity with the meaning of probability statements. Finally, a somewhat different type of uncertainty—experiential uncertainty—derives from the limits on a person's ability to imagine life under very different circumstances. This ability is very important to many treatment decisions but is difficult to exercise in the absence of prior experiences that are similar to present choices in the relevant dimensions.

In some cases, the problems raised by uncertainty can be resolved in an acceptable fashion. In the Commission's work on *Defining Death*, for example, the accuracy and certainty with which a determination of death can be made by various methods permitted the Commission to incorporate a brain-based standard into its "definition" of death. Testimony from medical experts and reviews of the scientific literature revealed that, when used in appropriate combinations, available procedures for determining death by brain criteria have only an infinitesimal chance of leading to an erroneous diagnosis. The benchmark is not absolute certainty but an extremely high degree (with doubts resolved toward a diagnosis of continued life rather than of death). In other words, the brain-based criteria are acceptable not because they are infallible but because they are at least as accurate as the more familiar cardiopulmonary tests, which are themselves extremely reliable. In order to reduce the empirical uncertainty created for individual physicians in diagnosing death, the Commission promoted the preparation of a single, brief, up-to-date statement of medical criteria to offer authoritative guidance to practitioners.

In contrast, the Commission found in its work on *Deciding to Forego Life-Sustaining Treatment* that the prognosis for some seriously ill newborns is so clouded with such uncertainty that the course of treatment that will give them the greatest benefit is inherently ambiguous. In light both of respect for persons and of well-being, the Commission found that decisions for these patients should rest with the individual's parents, in concert with the caregivers and subject to appropriate intrainstitutional review. It did not seem either feasible or appropriate, however, to set forth a single standard or definition, in the face of the uncertainties.

Sometimes the Commission found that uncertainties go beyond the empirical or probabilistic. The several different types of uncertainty that were found to underlie public uneasiness about genetic engineering illustrate this point.

Besides uncertainty over whether an event will occur, there is also uncertainty about the acceptability of various outcomes (termed evaluative uncertainty) and about how the new technology might alter fundamental notions of humanity and its responsibilities (conceptual uncertainty). For example, should genetics research aimed at adding "positive" traits to human beings be pursued? Would the ability to manipulate genes change the concept of responsibility to future generations? These are the sorts of issues for which there are no "answers" in the usual sense, based for example, upon the results of experiments; they are, however, issues that must be explored and answers sought in the realm of values. The Commission found uncertainties of this sort not only in the report on *Splicing Life* but throughout its work.

The Commission's work on genetic engineering also illustrated another role of uncertainty—not as a confounding variable in understanding concepts or weighing values, but in making choices based upon the "risks" of harm involved. An overabundance of awe and dread in the face of uncertainty can invite paralysis. A functional response is to recast the sometimes existential questions in ways that are more manageable. As one former member of the Commission has observed,

The issues are operationalized and reduced so that they can be analyzed and decided upon in the framework of existing scientific, technological, legal and ethical theory, knowledge and procedures.¹³

Thus, uncertainty causes a flight to experts—yet it also weakens the foundations on which deference to expertise rests.

In addition to the miasma of uncertainty that clouds technical knowledge, reliance on expertise faces a second problem: the tendency to confound technical matters with matters of social or ethical judgment. "Facts" and "values" are intertwined in many ways and at many levels in all decisions. It seemed to the Commission, however, that there are some instances in which it is possible, as a practical matter, to separate them; when that cannot be done, decisionmakers can at least be alert to the risks of converting questions of "ought" into questions of "is" by asking "experts" to make value judgments rather than only factual judgments. This issue may become more pronounced if "ethical experts" are called upon for value judgments by public bodies.¹⁴

In *Defining Death*, the Commission held to be well founded the traditional deference accorded physicians' exper-

¹³ Renée C. Fox, *The Evolution of Medical Uncertainty*, 58 MILBANK MEMORIAL FUND Q./HEALTH AND SOCIETY 1 (1980).

¹⁴ See Richard Delgado and Peter McAllen, *The Moralists as Expert Witness*, 62 B.U.L. REV. 869 (1982).

tise in diagnosing death in particular cases and in establishing criteria for the existence or nonexistence of particular biological functions. However, in making the societal choice about the standards for judging who is to be regarded as alive and who dead, the values and opinions of people beyond the medical community become relevant. Similarly, in its study of life-sustaining treatment, the Commission discussed the role technical criteria have played in decisions to withdraw life support from seriously ill newborns. In assessing proposals that such decisions should be based solely on a series of clinical observations (such as birth weight, extent of deformity or illness, and so forth) the Commission cautioned against "medicalizing" what are actually value judgments.

Society relies on experts not only because of their knowledge, experience and ability to simplify complex and sometimes threatening decisions, but also because of its trust in the objectivity that is a hallmark of the scientific method. Yet scientists are only human and as such may have motivations other than the unalloyed passion to find truth that is scientific ideal.¹⁵ In *Splicing Genes*, the Commission noted a particular problem for society in obtaining disinterested scientific advice about the impact of genetic engineering, if a very large proportion of the most knowledgeable scientists become directly involved in the commercial development of the field. Accommodating the divergent values of commerce and academe will be a challenge for genetic engineers in coming years; it will also be a matter of concern for society if it wishes to pursue the benefits of this burgeoning field without either encountering avoidable harm or adopting undue restrictions out of fear of such harm.

Public Versus Private Decisions. Decisions about medical care and research have traditionally been regarded as private matters, to be made by a patient and his or her physician alone or perhaps in consultation with members of the patient's family, friends, spiritual counselors, and other health care personnel. Now that "bioethics" is more frequently discussed in public settings, the issues involved also come up for more explicit attention in individual physician-patient decisionmaking. But the increased role of the public in this previously private sphere is not limited to this indirect effect; steps have

¹⁵ Being human, scientists are subject to conflicting—and sometimes overriding—motivations. When this happens, as in the case of research fraud, the scientific community—and society as a whole—suffer. See, e.g., President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *PROTECTING HUMAN SUBJECTS*, U.S. Government Printing Office, Washington (1981) at 177-92 (*Appendix E, Case Studies: Five Incidents of Alleged Misconduct in Biomedical Research*).

been taken and more are urged to involve people outside family and friends in individual biomedical decisions.

Nothing has occurred to indicate that individuals are less concerned about privacy—indeed, if anything, public concern over invasions of privacy has increased in recent years as a result of electronic data storage and retrieval. Yet the Commission in its studies frequently heard arguments for involving people from outside the physician-patient relationship in health care decisionmaking. In certain cases, strong reasons can be given for broadening the range of participants in decisionmaking—but the Commission also found that this broadening places stress on time-honored assumptions about health care and poses challenges for policymakers to develop new means of reaching health care decisions that manage to preserve the important values served by the traditional, private locus.

Some of the tension between public and private decision-making can be reduced by separating the stages in the process—from the formulation of policy to its implementation and review.¹⁶ The greatest sensitivity attaches to the middle stage. By contrast, a role is often recognized for public representatives (or at least for people other than the parties directly affected) in policy formulation and sometimes in review of decisions. For example, in light of the rapid escalation of health care expenditures and costs, the interest of the general public in policies to avoid wasteful and inefficient treatment is generally recognized, whereas public participation in case-by-case decisions at the bedside, as it were, is less readily welcomed.¹⁷

¹⁶ See Katz and Capron, *supra* note 9, at 153-55.

¹⁷ In the health care financing arena, outsiders now participate primarily in after-the-fact review, which can be aimed either at deciding how the costs of treatment will be borne (*e.g.*, whether they will be reimbursed by a patient's health insurance or public program) or at influencing a practitioner's decisions by drawing the person's attention to his or her aberrations from prevailing norms.

In some cases, the involvement of third parties might be even more direct, in order to encourage physicians to consider the interests of the larger society in recommending treatment alternatives to patients. The Commission recognized the legitimate concerns of society over the current escalation in the costs of health care, but it was particularly concerned that in those areas involving the greatest costs—namely, intensive treatment of dying patients—a conflict could easily arise between the government's traditional role as protector of the helpless and its championing of the public's interest in reduced expenditures. For this reason, the Commission placed highest priority on attempting to resolve some of the pressing ethical issues that already make decisionmaking about life-sustaining care so difficult—

The strongest arguments for enlarging the circle of participants arise when vital interests are at stake for a party who is unable to protect him or herself (such as a newborn child) and when there are conflicting claims on the loyalties of some or all of the parties who would normally reach decisions privately. *Deciding to Forego Life-Sustaining Treatment* reports on the steps that hospitals have taken to establish "ethics committees." Because of the importance of the well-being and respect principles, the Commission endorses, for example, the review by such an intrainstitutional body of all decisions to cease life-sustaining care of a newborn. Although this conclusion favors the involvement of people besides the baby's parents and pediatrician in the decision, it represents a less public means of review than the method now commonly adopted—namely, recourse to the courts. The Commission found that a mechanism that is physically closer to where the decision must be made is more likely to be sensitive to the personal values involved, aware of the changing medical situation, and able to respond quickly. This was one area in which the Commission concluded that an intermediate-level institution is needed for some decisions, a level between the totally private and the totally public.¹⁸

The grounds for mandating such participation are particularly strong when the public has a direct interest in the actions being taken. Typically, the reason for including additional people in decisionmaking is to provide greater protection for the patient or subject involved. For example, for nearly two decades the Public Health Service—with increasing degrees of regulatory specificity—has required advance consideration of the protocols for government-supported research by people other than solely the investigator and the subjects he or she invites to participate in the research.

Occasionally, the people directly involved in private decisions initiate the process of having the decision made with public participants. As the Commission saw in studying gene splicing, researchers in molecular biology took the lead in alerting others—first their scientific peers and then the general public—to the potential implications of their investigations. The result of this unusual step was the creation of a Federal committee to oversee the Federally funded gene splicing research; as the hazards of this work were reevaluated over time, the decisionmaking process was gradually decentralized and returned in large measure to the judgment of the professionals working in the field.

before the pressure to reformulate such decisionmaking processes in light of resource constraints adds further complications.

¹⁸ For an examination of the way certain issues shift over time from private to public settings, see Albert O. Hirschman, *PRIVATE INTEREST AND PUBLIC ACTION*, Princeton Univ. Press, Princeton (1982).

The Commission's Role and Objectives

The issue of public participation in decisionmaking is relevant, the Commission realizes, to an evaluation of its own role as a panel created by Congress and responsible to the public. By examining an issue, the Commission did not necessarily signal that the subject was primarily one for public participation. Rather, the Commission's objective seldom was to recommend regulations or legislation, which would increase public involvement in the decisions, nor even to prescribe a particular outcome as "ethical," but rather to point to the considerations that the private parties could weigh in reaching their own judgments.

This does not mean that the Commission aimed only for generalities. Whenever it was possible to make a substantive judgment on a class of cases, taking into consideration the interests, values, parties, and considerations at stake, the Commission did so. Often it was necessary to distinguish issues of fact from conceptual and value questions and to obtain empirical information (for example, the state of the art of a particular science; current attitudes and practices with respect to a particular disorder; demographic data concerning incidence, treatment, and outcome of a condition).

When the Commission was unable to articulate substantive rules that would clearly apply to all (or most) cases present in a certain issue, it tried to identify the factors that ought to be taken into account during decisionmaking, as well as the process by which decisions should be made. At times, it was also possible to state the outer limits beyond which decisions would be deemed unacceptable. Placing such limits on the range of possible choices can provide some guidance for decisionmaking in the future, especially if the rationale underlying the recommendation is clearly set forth.

In its conclusions and recommendations, the Commission has addressed a variety of levels. At times, the appropriate response to a problem is enactment of legislation, as the Commission recommended in *Defining Death* (a uniform law) and in *Making Health Care Decisions* (laws providing means for patients to express directions about care prior to becoming incompetent). Similarly, in *Screening and Counseling for Genetic Conditions*, the Commission suggested that adoption laws be changed to give adoptive families access to genetic information and that genetic histories of donors for artificial insemination be universally required. At other times, a response by an administrative agency is more appropriate, as the Commission suggested in its reports *Protecting Human Subjects*, *Implementing Human Research Regulations*, and *Compensating for Research Injuries*.

Often, however, less formal approaches are preferable. It may be that leadership by a professional society or by

academic institutions will accomplish what is necessary. Thus, for example, the Commission recommended that curricula in medical and nursing schools provide better instruction in the important aspects of good communication with patients. It is also recommended that health care professionals involved in genetic counseling be better prepared to deal with the sensitive ethical issues that arise in that field. In the area of biomedical and behavioral research, the Commission emphasized the importance of assisting members of Institutional Review Boards (IRBs) to better understand their responsibilities for protecting human subjects. To that end, the Commission developed a Guidebook for IRBs and also suggested that HHS implement a program of site visits to assess the performance of IRBs as well as to provide guidance for improvement. In the field of genetic engineering, the Commission perceived that it is the general public that is most in need of improving their understanding of the possibilities and limitations present in developing technologies and of their implications.

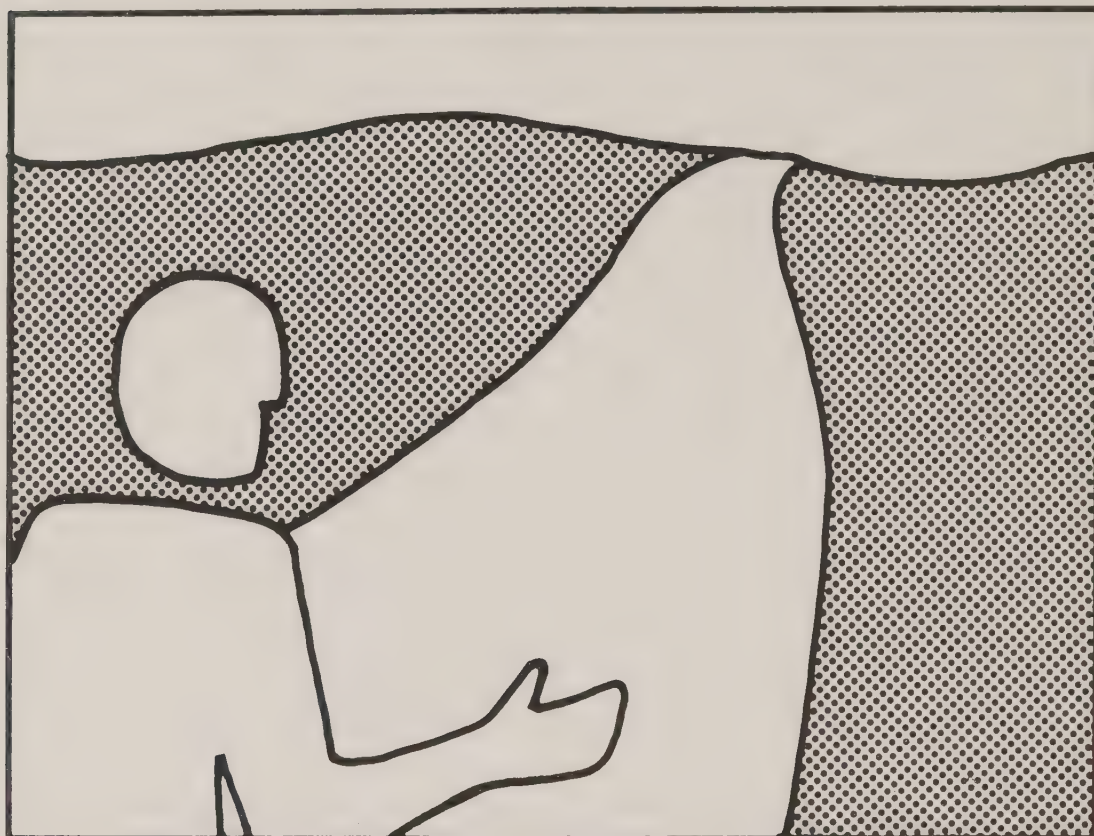
Finally, when the data were inadequate for a policy recommendation, the Commission recommended that a matter receive further study. It suggested, for example, that HHS sponsor a small experiment to try out possible approaches to providing compensation for research injuries, and it recommended that hospitals not only adopt but carefully evaluate various approaches to the use of "ethics committees" to assist in decisionmaking about life-sustaining therapy. It also suggested that more information be obtained on the effects of family involvement in the consent process and on ways to determine an individual's decisionmaking capacity.

Sometimes the Commission recommended procedures for decisionmaking on a case-by-case basis (for example, the use of ethics committees in hospitals or a national commission to guide developments in genetic engineering). Occasionally, such recommendations were accompanied by guidelines for making decisions as well (such as the conclusion that ethics committees reviewing decisions to forego treatment of a newborn baby always ascertain that the benefit of treatment versus nontreatment has been judged from the vantage point of the child). Finally, at times the Commission merely stated general conclusions, setting forth standards by which to judge the ethical acceptability of certain decisions (such as equitable standards regarding access to health care).

Looking to the Future

Since biomedical science and practice undergo continuous development, static rules would be as unwise as they are unachievable. The President's Commission has examined a number of bioethical issues that seemed to the Congress, the President, and the Commission itself to press for attention and

resolution today. In a little more than three years of study, however, this Commission has had no thought of either exhausting the range of important concerns that deserve to be addressed or of closing the book on the issues it has studied.



On some of its topics, the Commission has specifically suggested that means be found to continue the process of scrutiny and recommendation. For example, in its Second Biennial Report on the rules governing research with human subjects, the Commission noted the need for one or more oversight bodies, both to aid decisionmakers in resolving ethical issues raised by particularly sensitive research projects (a role briefly fulfilled by the Ethics Advisory Board in DHHS, for example) and to ensure that the Federal rules and their implementation continue to achieve an appropriate balance between advancing science and protecting human subjects. Similarly, the Commission proposed several alternative means through which the ethical and social evaluation of genetic engineering that it has begun can be continued—an evaluation that will be needed as the impact of that rapidly progressing field comes to be more widely felt in society.

If the President and Congress were to decide to constitute another body with a broad mandate in bioethics, the present Commission believes that its agenda ought not to be too fixed, so that it can take on those subjects that are most urgent and significant at the time. There need be no concern that such a body would need to search for issues. For example, medical interventions over the last several decades in human reproduc-

tion have raised a number of issues that have never been fully addressed, much less resolved:

- Artificial insemination, which has been used in human beings for many years, is now involved in tens of thousands of births each year. Yet the chaotic state of the law on this subject, as well as disagreement about the relevant ethical considerations, has led to practices—such as partial or nonexistent record-keeping by many of the physicians involved—that are neither good medicine nor good ethics.
- In the past several years, American physicians have successfully performed human *in vitro* fertilization and embryo implantation, and the number of couples in treatment each year is increasing swiftly. The potential now exists for the chaos surrounding artificial insemination being repeated with egg donors and borrowed wombs. Such developments seem likely in light of what has been described as a “boom in surrogate mothers.”¹⁹ In the past several years, a network of women, physicians, and lawyers has developed that can arrange for a “surrogate mother” for couples with female infertility. The shock many people feel at this development may have contributed to society’s failure to produce an ethically and legally coherent response that would provide appropriate protection to the interests of all involved, most particularly any children produced.
- Many of the biomedical advances in this area have important implications for children, born and unborn. These implications extend beyond matters of their physical health (for example, increasingly sophisticated and wide-ranging means of antenatal diagnosis of genetic disorders, the repair of an organic defect while a child is still in the womb, and so forth) to the ethical and legal conception of human beings at various points in the process of reproduction, development, and birth.

At the opposite end of the spectrum of life, the attention of patients, physicians, and the guardians of the public purse is focused on efforts to forestall imminent death through intensive medical, surgical, and nursing care. Within the foreseeable

¹⁹ See, e.g., Carol Krucoff, *Focus: The Surrogate Baby Boom*, WASH. POST, Jan. 25, 1983, at C5; Jay Mathews, *Surrogate Motherhood Becoming an American Growth Industry*, WASH. POST, Jan. 24, 1983, at A2; *When Women Bear Children for Others*, N. Y. TIMES, Dec. 22, 1980, at B6; George F. Will, *Surrogate Mothers*, WASH. POST, Dec. 14, 1980, at C7; *Delivery of Surrogate Mother’s Baby Is Reported*, N. Y. TIMES, Dec. 11, 1980, at A25; Theresa M. Mady, *Surrogate Mothers: The Legal Issues*, 7 AM. J. L. & MED. 323 (1982).

future, however, it may become possible to slow down the aging process—a prospect with profound implications for society.²⁰

The discoveries currently being made in the neurosciences also portend profound ethical, social, and legal issues. Traditional notions of personal responsibility and blame may need to be rethought in light of greater understanding of brain chemistry; likewise, an ability to alter not merely mood but also thoughts and feelings would plainly represent a power with great potential for harm as well as benefit, and one not easily confined to the controlled environment of medical care settings.

Nor are the issues that might come before a subsequent commission on bioethical issues likely to be generated solely by startling discoveries along the frontiers of the life sciences. Some may be matters of perennial concern, such as the questions raised by various medical interventions with mentally handicapped people, inside or outside of institutions. Others arise not in the microcosm of the individual patient-practitioner relationship but in the larger society, such as the concern voiced recently by medical leaders over the effects of a huge new industry that supplies health-care services for profit.²¹

In a pluralistic society, a commission on bioethical issues can serve as more than a forum for the airing of differences on matters of concern, and more even than as a catalyst to force a closer look at the unexamined ways that health care decisions have traditionally been made. It can also articulate the broad area of agreement that already exists in this country on most of the issues at stake—and it can, if it is fortunate, provide the means for enlarging the field of common agreement and for reassuring those who daily face the challenges of making bioethical decisions as patients, professional, or public servants. Finally, a commission on bioethics can play an important part in engendering and encouraging the process by which a vibrant and ever-developing society reexamines, revises, and reaffirms its system of values and belief—a system in which the issues of medicine and research are significant but not alone.

²⁰ See Committee on the Life Sciences and Social Policy, National Research Council, *ASSESSING BIOMEDICAL TECHNOLOGIES: AN INQUIRY INTO THE NATURE OF THE PROCESS*, National Academy of Sciences, Washington (1975) at 59-78.

²¹ Arnold S. Relman, *The New Medical-Industrial Complex*, 303 *NEW ENG. J. MED.* 963 (1980).

Biographies of the Commissioners

A

Morris B. Abram (Chairman) is a New York attorney, former President of Brandeis University, and an advocate of human and civil rights. He has served previously at the behest of United States Presidents in various capacities. President John F. Kennedy appointed him as First General Counsel to the Peace Corps in 1961 and President Lyndon B. Johnson named him to serve as the U.S. Representative to the United Nations Commission on Human Rights between 1965 and 1968.

Mr. Abram has assumed other prominent civic positions as well. He has been President of the American Jewish Committee, a member of the U.S. Subcommittee on Prevention of Discrimination and Protection of Minorities, and long-time Chairman of the United Negro College Fund. In addition, he has served as a member of the Mt. Sinai Hospital Human Subjects Review Panel.

Mr. Abram is presently practicing law in New York City as a partner in the firm of Paul, Weiss, Rifkind, Wharton, and Garrison. He is a native of Atlanta, a former Rhodes Scholar, and a graduate of the University of Chicago Law School.

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H. Thomas Ballantine, Jr., is Clinical Professor of Surgery of Harvard Medical School and Senior Neurosurgeon at Massachusetts General Hospital. Dr. Ballantine has served as President of the Massachusetts Medical Society and as a member of the Board of Directors of Blue Shield of Massachusetts and the Board of Governors of the American College of Surgeons. He was chosen to deliver the 1979 Discourse at the Annual Meeting of the Massachusetts Medical Society. He has

also written over the last ten years on social, economic, and ethical problems in medicine.

Dr. Ballantine graduated from Princeton University (B.S., 1933) Johns Hopkins University Medical School (M.D., 1937), and the University of Michigan (M.S., 1947), and received an honorary degree from Suffolk University (D.Sc., 1969).

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George R. Dunlop is Consulting Surgeon at the Memorial Hospital in Worcester, Mass., and Professor of Surgery at the University of Massachusetts Medical School. He has assumed leadership positions in medically related organizations, both at the state and national levels. Dr. Dunlop currently serves as a member of the Board of Commissioners of the Joint Commission on Accreditation of Hospitals. He also sits on the Boards of Directors of the Worcester Foundation for Experimental Biology and the American Cancer Society Massachusetts Division, organizations he formerly chaired.

Dr. Dunlop is Past President of the American College of Surgeons and Past Chairman of the Board of the National Association of Blue Shield Plans. He received a B.S. degree from the University of Cincinnati in 1927 and a medical degree from Harvard Medical School in 1931.

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Renée Claire Fox is a University of Pennsylvania sociologist. Her experience in the dual areas of ethics and health care is extensive. She has been a member of the Ethics Committee of the Institute of Medicine of the National Academy of Sciences. In addition, she is a Fellow of the Institute of Society, Ethics and the Life Sciences and is a founding member of the Institute of Intercultural Studies. Dr. Fox also serves as a member of the Board of Directors of the American Association for the Advancement of Science.

She is the author of numerous articles. Her books include *Experiment Perilous* (published in 1959), *The Emerging Physician* (published in 1959), *Essays in Medical Sociology - Journeys Into the Field* (published in 1979), and *The Courage to Fail*, coauthored with Judith Swazey (published in 1974).

Dr. Fox has taught in various universities since receiving her Ph.D. from Harvard University in 1954. She is currently Annenberg Professor of Social Science at the University of Pennsylvania, with appointments in the Department of Psychiatry and Sociology. She chaired the latter department from 1972 to 1978.

Mario García-Palmieri served as the Puerto Rican Secretary of Health from 1967 to 1968, and is currently Professor and Head of the Department of Medicine at the University of Puerto Rico. He has received many honors for his work in cardiology. Since 1980, he has been elected President of the American Society of Cardiology, appointed to the Board of Trustees of the Interamerican College of Physicians and Surgeons, and awarded the International Achievement Award of the American Heart Association. Dr. García-Palmieri is the author of a book and over 100 scientific papers, and he is a frequent lecturer throughout the United States and Latin America.

A native Puerto Rican, Dr. García-Palmieri was born in Adjuntas in 1927. He earned his medical degree at the University of Maryland in 1951.

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Frances Kessler Graham is Hilledale Professor of Psychology and Pediatrics at the University of Wisconsin. For the majority of her professional career, she has done extensive research in addition to her teaching responsibilities. The respect afforded Dr. Graham by her colleagues is reflected in her selection as President of the Society of Psychophysiological Research and of the Society for Research in Child Development. In 1979, she was named to chair the American Association for the Advancement of Science's Section on Psychology.

Dr. Graham has written articles in distinguished journals virtually every year since 1943, with her most recent work focusing on reflex responsiveness. She received her Bachelor's Degree from Pennsylvania State University in 1938 and her Ph.D. from Yale University in 1942.

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Bruce Kelton Jacobson is Director of the Family Practice Residency Program at John Peter Smith Hospital in Fort Worth, Texas, and Associate Professor of Family Practice and Community Medicine at Southwestern Medical School. Dr. Jacobson has been active in both professional and civic organizations, serving on boards concerned with medical education, child abuse and neglect, rape, a local school district, and small business.

He graduated from Texas Christian University (B.A., 1950) and Baylor College of Medicine (M.D., 1954).

Albert Rupert Jonsen is Chairman of the Bioethics Group for the five University of California Schools of Medicine. He received his Ph.D. degree in Religious Studies from Yale University.

Dr. Jonsen is currently Professor of Ethics in Medicine at the University of California School of Medicine at San Francisco. His work in this field dates back to 1973 when he was a member of the Committee on Human Values in Health Care of the Institute of Medicine. From 1974 to 1978, he served as a member of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. He is currently a Fellow of the Institute of Society, Ethics and the Life Sciences, and of the Institute of Medicine of the National Academy of Sciences.

His most recent book, published in 1976, is *Ethics of Newborn Intensive Care*, and he is a frequent author of articles on ethics and health care delivery. Professor Jonsen is also on the editorial board of the *Journal of Religious Ethics*.

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Patricia A. King is a Georgetown University Law Professor. Her past and present activities in the area of biomedical ethics are extensive. She served as a member of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1974-78. She also testified before a House Subcommittee in 1977 on ethical issues in science research.

Professor King is a 1963 graduate of Wheaton College in Boston, Massachusetts and she received her law degree from Harvard Law School in 1969. She is currently a Fellow of the Institute of Society, Ethics and the Life Sciences and is a member of the Washington Area Seminar on Science, Technology and Ethics.

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Mathilde Krim is an associate member of the Sloan-Kettering Institute for Cancer Research. She is also the coordinator of Sloan-Kettering's International Laboratories for the Molecular Biology of Interferon Systems. She is on the Boards of Directors of the National Biomedical Research Foundation and the Institute of Society, Ethics and the Life Sciences. Dr. Krim is also a member of the National Endowment for the Humanities' Advisory Committee on Science, Technology, and Human Values.

She was appointed by President Lyndon Johnson to serve on the President's Committee on Mental Retardation, and has

been a consultant in the area of cancer research. Though an American citizen, she was born in Italy and educated at the University of Geneva in Switzerland.

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Donald N. Medearis is Chief of Children's Service at Massachusetts General Hospital and Professor of Pediatrics at Harvard University. He is a 1949 graduate of the University of Kansas. He received his medical degree from Harvard in 1953. Since that time, his professional activity has focused on the study of infectious diseases in children.

He has held academic and administrative posts at several medical schools. He taught at Johns Hopkins University, the University of Pittsburgh, and Case Western Reserve University before coming to Harvard in 1977. From 1965 to 1969 he was Medical Director of Children's Hospital in Pittsburgh, and from 1969 to 1974 he served as the Dean of the School of Medicine at the University of Pittsburgh.

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John J. Moran is President of the Houston-based Moran Foundation, which was established in 1970 to fund research in medicine. He is also the former owner of a company that developed diagnostic reagents and instruments for the professional medical community. He is a member of several professional societies specializing in clinical chemistry.

Mr. Moran graduated from the University of California at Santa Barbara (B.S., 1948) and attended the Graduate School at the University of California at Los Angeles.

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Arno G. Motulsky is an expert in the field of medical genetics and Professor of Medicine and Genetics at the University of Washington's School of Medicine in Seattle. He is director of the University's Center for Inherited Diseases and of the Genetics Clinic at the University Hospital, where he is also an attending physician in medicine. He has served as chairman of the Human Subject Policy Board at the University of Washington.

Dr. Motulsky is a member of the American Academy of Arts and Sciences, the National Academy of Sciences, and the Institute of Medicine, on whose Council he served between 1980-1982. His other professional activities have included officerships in the American Society of Clinical Investigation, the American Society of Human Genetics, and the Institute of

Society, Ethics and the Life Sciences. He is the author of many professional publications and the co-author of a major text, *Human Genetics: Principles and Approaches*, published in 1979.

Dr. Motulsky received his bachelor's and medical degrees from the University of Illinois and took his residency in internal medicine at Michael Reese Hospital in Chicago and his training in human genetics at University College in London, England.

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Daher B. Rahi is an osteopathic physician and surgeon in St. Clair Shores, Michigan. He is a former President of the Michigan Association of Osteopathic Physicians and Surgeons. He has also served as Director of the Michigan Statewide Professional Standards Review Council and as a member of the Michigan Health Occupations Council. He is a member of the Executive Committee, Chairman of the Professional Relations Committee, and a member of the Board of Directors of Blue Cross-Blue Shield of Michigan.

Dr. Rahi is a former County Commissioner, is very active in civic and international affairs, and has held leadership positions in many organizations, most notably as World President of the World Lebanese Cultural Union.

Dr. Rahi was born in Lebanon in 1930, and became a naturalized citizen of the United States in 1961. He earned a B.S. degree from the University of Detroit in 1953 and a D.O. from the College of Osteopathic Medicine and Surgery of Des Moines, Iowa, in 1957.

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Frederick Carl Redlich is a UCLA Psychiatry Professor and former Yale Medical School Dean. He is the former Director of the Behavioral Sciences Center at Yale University, and was also a Professor of Psychiatry at Yale's Medical School. He is a Fellow of the Institute of Society, Ethics and the Life Sciences.

He is a naturalized citizen, having been born in Vienna, Austria, in 1910. Dr. Redlich received his M.D. degree from the University of Vienna in 1935.

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Anne A. Scitovsky is Chief of the Health Economics Divisions at the Palo Alto Medical Research Foundation. She is a 1937 graduate of Barnard College. She pursued her studies at

the London School of Economics and earned a Masters Degree in Economics from Columbia University in 1941.

She has published extensively in the area of health economics, including papers for the former Department of Health, Education, and Welfare and for the World Congress on Health Economics. Her most recent work has focused on the demand for physician's services and on the cost of medical care.

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Seymour Siegel is Professor of Ethics and Theology at the Jewish Theological Seminary of America and Professor of Humanities in Medicine at the Medical College of Pennsylvania. He is President of the American Jewish Forum, a member of the Executive Board of the New York Jewish Relations Council, and a member of the Board of the Jewish Publication Society. He is also a Fellow of the Kennedy Institute of Ethics at Georgetown University, an Adjunct Scholar of the Heritage Foundation, and serves on the Boards of the American Family Institute and The Ethics and Public Policy Center.

Rabbi Siegel was for ten years the Chairman of the Committee on Jewish Law and Standards of the Rabbinical Assembly, the international organization of Conservative Rabbis. He was also a Guest Scholar at the Woodrow Wilson International Center for Scholars. He is the author of books and articles on Jewish ethics. His latest publication is *Medical Ethics from a Jewish Perspective*. Rabbi Siegel was ordained in 1951 at the Jewish Theological Seminary.

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Lynda Hare Smith is a member of the University of Colorado Health Science Advisory Committee in Denver and a member of the Advisory Board to the Chancellor of the University of Colorado in Colorado Springs. She is also a volunteer counselor and a volunteer for newborn aural testing at Penrose Hospital in Colorado Springs. She is active in the Episcopal Church, having served as Past President of the Episcopal Women's Association in Colorado Springs.

Mrs. Smith graduated from the University of Texas with a B.S. degree in 1962.

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Kay Toma is a physician in private practice and President of the Bell Medical Center in Bell, California. He served eight years on the California Board of Medical Examiners, is a past

President of the Bell Chamber of Commerce, and is a Fellow of the Royal Society of Health of London.

In 1977, Dr. Toma was chosen "Man of the Year" by the Lebanon Syrian American Society and in 1981, he received the same honor from the U.S. Omen. He received his bachelor's degree from the University of Oklahoma and his medical degree from the University of Tennessee in 1941.

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Charles J. Walker is a Nashville physician. He is a 1938 graduate of South Carolina State University. Five years later, he received his medical degree from Meharry Medical College.

Dr. Walker holds many professional affiliations, both past and present. He is former President of the South Street Community Center and served as a member of the Executive Board of the Nashville Human Relations Council. He is a former member of the Board of Trustees of Fisk University, and is on the Board of Governors of the Matthew Walker Community Health Center.

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Carolyn A. Williams is a faculty member in the Department of Epidemiology, School of Public Health, and in the School of Nursing at the University of North Carolina at Chapel Hill. Professor Williams is a Fellow of the American Academy of Nursing and of the American Public Health Association. She chairs the Research Advisory Committee of the American Nurses Foundation and is a member of the Commission on Research of the American Nurses Association. Professor Williams received her B.S. in 1961 from Texas Womens' University, her M.S. in public Health Nursing in 1965 and her Ph.D. in Epidemiology in 1969, both from the University of North Carolina. In addition, she has studied ethics and philosophy at the Southwestern Baptist Theological Seminary. She has written widely on nurses' contributions to health care, community nursing, and ethical issues in health care policy.

Statutory Categories

B

Five commissioners from the fields of ethics, theology, the natural sciences (other than a biomedical or behavioral science), the social sciences, the humanities, health administration, government, and public affairs:

1. Morris B. Abram, J.D., LL.D., *Law*
(July 1979 - Mar. 1983)
2. Renée C. Fox, Ph.D., D.H.L., *Medical Sociology*
(July 1979 - Feb. 1982)
Seymour Siegel, D.H.L., *Theology*
(Feb. 1982 - Mar. 1983)
3. Albert R. Jonsen, S.T.M., Ph.D., *Ethics*
(July 1979 - Aug. 1982)
Kay Toma, M.D., *Medicine*
(Aug. 1982 - Mar. 1983)
4. Patricia A. King, J.D., *Law*
(July 1979 - May 1980)
Carolyn A. Williams, Ph.D., *Health Administration and Nursing*
(Sept. 1980 - Aug. 1982)
H. Thomas Ballantine, Jr., M.D., M.S., D.Sc., *Neurosurgery*
(Aug. 1982 - Mar. 1983)
5. Anne A. Scitovsky, M.A., *Economics*
(July 1979 - Aug. 1982)
John J. Moran, B.S., *Business*
(Aug. 1982 - Mar. 1983)

Three commissioners from biomedical or behavioral research:

6. Arno G. Motulsky, M.D., *Genetics*
(July 1979 - Mar. 1983)
7. Mathilde Krim, Ph.D., *Molecular Biology*
(July 1979 - Oct. 1981)

Lynda Hare Smith, B.S., *Housewife*
(Mar. 1982 - Mar. 1983)

8. Fritz C. Redlich, M.D., *Psychiatry*
(July 1979 - Feb. 1980)

Frances K. Graham, Ph.D., *Psychology*
(May 1980 - Jan. 1982)

Daher B. Rahi, D.O., *Osteopathic Medicine*
(Feb. 1982 - Mar. 1983)

Three commissioners from the practice of medicine:

9. Charles J. Walker, M.D., *Internal Medicine*
(July 1979 - Mar. 1983)

10. Mario García-Palmieri, M.D., *Cardiology*
(July 1979 - Aug. 1982)

Bruce Kelton Jacobson, M.D., *Family Medicine*
(Aug. 1982 - Mar. 1983)

11. Donald N. Medearis, M.D., *Pediatrics*
(July 1979 - Feb. 1982)

George R. Dunlop, M.D., *Surgery*
(Feb. 1982 - Mar. 1983)

Witnesses and Consultants

C

T = Testimony; P = Public Comment; C = Consultants

Terrence Ackerman (T, 1/9/81)

Assoc. Prof. of Medical Ethics and Assoc. Director,
Program on Human Values and Ethics, Univ. of Tenn.
Center for the Health Sciences; representing the Assoc.
of Amer. Cancer Institutes

Lu Ann Aday, Ph.D. (T, 3/13/81)

Senior Research Assoc., Center for Health Admin.
Studies, Univ. of Chicago

Dr. Duane Alexander (C, *IRB Guidebook*)

Deputy Director, National Institute of Child Health and
Human Development, NIH

Jan Almquist, J.D. (C, Privacy; T, 3/13/82)

Attorney, Musick, Peeler, and Garret, Los Angeles

Nini Almy (C, IRB site visit)

Univ. of Ill.

Dr. Stuart Altman (T, 9/10/82)

Dean, Florence Heller Graduate School, Brandeis Univ.;
former Deputy Asst. Secretary of HEW

Dr. French Anderson (C, *Splicing Life*; T, 7/10/82)

Chief, Laboratory of Molecular Hematology, National
Heart, Lung and Blood Institute, NIH

Earl Appleby (P, 10/9/82)

Staff, Office of Sen. Jesse Helms; testified on his own
behalf

Dr. John Arnold (T, 9/15/80)

Director, Quincy Research Center, Kansas City, Mo.

Mila Aroskar (C, *Care Decisions*)

Assoc. Prof., School of Public Health, Univ. of Minn.

Dr. Peter Auld (T, 1/9/82)

Neonatologist; Director, Neonatal Intensive Care Unit,
New York Hospital

Nancy Azarian (C, IRB site visit)

Children's Hospital Medical Center, Boston

Dr. Backer (P, 6/4/81)

Physician, Worcester, Mass.

Patricia Balassone, R.N., M.S. (T, 4/3/82)

Research Fellow, Primary Care Programs, Univ. of Md.,
Baltimore

Dr. John Ball (P, 9/10/82)

Representing the Amer. College of Physicians

David Baltimore, Ph.D. (C, *Splicing Life*)

Prof. of Microbiology, Mass. Institute of Technology

Dr. H. David Banta, M.P.H. (T, 10/22/81)

Asst. Director, Health and Life Sciences Division, Office
of Technology Assessment, U.S. Congress

Albert A. Barber, Ph.D. (T, 9/11/81)

Vice Chancellor for Research Programs, Univ. of Calif.,
Los Angeles

Bernard Barber, Ph.D. (C, IRB site visit, *Protecting
Subjects*)

Dept. of Sociology, Barnard College

Dr. Jesse Barber (C, *Defining Death*)

Chairman, Dept. of Neurosurgery, Howard Univ. Hospital

Sister Corinne Bayley (T, 9/12/81)

Director of bioethics teaching for a group of hospitals in
Calif.

Dr. Robert J. Beall (T, 5/8/81)

National Director, Cystic Fibrosis Foundation

Tom Beauchamp, Ph.D. (T, 7/10/81)

Senior Research Scholar, Kennedy Institute, Georgetown
Univ.

Dr. Donald P. Becker (C, *Defining Death*)

Chairman, Division of Neurological Surgery, Va.

Commonwealth Univ., Medical College of Va., School of
Medicine

Dr. Richard E. Behrman, J.D. (C, *Defining Death*)

Dean, Case Western Reserve Univ. School of Medicine

Robert Belair, J.D. (T, 3/14/81)

Attorney, Wash., D.C.; former Counsel to the Natl.

Comm. on the Confidentiality of Medical Records

Fred Benjamin (P, 12/15/82)

Dept. of Transportation; testified on his own behalf

Alan Bennett, J.D. (T, 3/14/81)

Attorney; former Special Counsel to the Minority, U.S.

Senate Comm. on Governmental Affairs

Dr. Donald R. Bennett (C, *Defining Death*)

Chairman, Dept. of Neurology, Univ. of Neb. College of
Medicine; Chairman, Dept. of Obstetrics and Gynecology,
Creighton Univ. School of Medicine

- Dr. H. Richard Beresford, J.D. (C, *Defining Death*)
Dept. of Neurology, North Shore Univ. Hospital,
Manhasset, N.Y.
- George K. Bernstein, LL.B. (C, *Compensation*; T, 5/16/80,
1/9/81)
Attorney, Wash., D.C.; former Federal Insurance
Administrator
- James Bernstein (T, 4/3/82)
Chief, Office of Rural Services, N.C. Dept. of Human
Services, Raleigh
- Dr. Reginald G. Bickford (C, *Defining Death*)
Dept. of Neurosciences, Univ. of Calif., San Diego,
School of Medicine
- Dr. William A. Black, Jr. (C, *Defining Death*)
Northwestern Neurological Associates Inc., Scranton,
Penn.
- Dr. David A. Blake (C, *IRB Guidebook, Protecting
Subjects*)
Asst. Dean for Research Programs and Assoc. Prof. of
Obstetrics/Gynecology and of Pharmacology, Johns
Hopkins Univ. School of Medicine
- Rabbi J. David Bleich (T, 7/11/80)
Assoc. Prof. of Talmudic and Jewish Law, Yeshiva Univ.,
New York; representing Agudath Israel and the Union of
Orthodox Jewish Congregations of America
- Dr. Robert Blendon, (T, 9/10/82)
Senior Vice President, Robert Wood Johnson Foundation,
Princeton, N.J.; former Special Asst. to the
Undersecretary of HEW
- Samuel Bloom, Ph.D. (T, 4/3/82)
Prof. of Sociology and of Comm. Medicine, Mt. Sinai
School of Medicine of the City Univ. of New York
- Dr. Daniel S. Blumenthal (P, 4/3/82)
Pediatrician, Morehouse School of Medicine
- James Blumstein, J.D. (T, 11/13/81)
Vanderbilt Univ. School of Law
- Dr. Benjamin Boshes, Ph.D. (C, *Defining Death*)
Dept. of Neurology, Northwestern Univ. Medical School
- Dr. Harry Bostrom (T, 9/15/80)
Prof. of Medicine, Univ. of Uppsala, Sweden
- Dr. Maxwell Boverman (T, 12/11/81)
Psychiatric consultant to NIH
- Bernard R. Boxill (T, 9/15/80)
Asst. Prof. of Philosophy, Univ. of South Fla.
- Jonathan Brant, J.D. (T, 6/4/81)
Assoc. Prof. of Law, New England College of Law
- Dr. Philip Braunstein (C, *Defining Death*)
Prof. of Radiology, Univ. of Calif., Irvine, Calif. College
of Medicine

- Dr. Halyna Breslawec (P, 12/15/82)
Food and Drug Admin.
- Dan W. Brock, Ph.D. (T, 1/10/81)
Prof. of Philosophy, Brown Univ.
- Judy Brown (T, 1/9/82)
Nurse practitioner, Intensive Care Nursery, Children's Hospital, Wash., D.C.
- Dr. Norman K. Brown (T, 9/12/81)
Physician, Seattle, Wash.
- E. Richard Brown, Ph.D. (T, 11/13/81)
Univ. of Calif., Los Angeles, School of Public Health
- Dr. Marshall J. Brumer (T, 4/9/81)
Pulmonary specialist; one of Mr. Perlmutter's doctors
- Robert A. Brungs, S.J. (C, *Splicing Life*)
Director, Institute for Theological Encounter with Science and Technology, St. Louis, Mo.
- Allen Buchanan, Ph.D. (T, 10/22/81)
Assoc. Prof. of Philosophy, Univ. of Minn.
- Carol Buder (C, *Care Decisions*)
Asst. Prof., Georgetown Univ. School of Nursing
- Dr. John T. Burroughs, J.D. (C, *Defining Death*)
Chief, Division of Medical Legal Research, Dept. of Legal Medicine, Walter Reed Hospital, Wash., D.C.
- Robert Burt (T, 6/10/82)
Prof. of Law, Yale Law School
- Dr. Russell Butler (C, *Defining Death*)
Concord, Mass.
- Harry Byer, J.D. (P, 6/4/81)
Attorney, Center for Law and Health Sciences, Boston Univ.
- Dr. Daniel Callahan (T, 6/10/82)
Director, Hastings Center, Hastings-on-Hudson, N.Y.
- Arthur L. Caplan, Ph.D. (P, 3/12/82)
Assoc. for the Humanities, Hastings Center, Hastings-on-Hudson, N. Y.
- Dr. Philippe V. Cardon (P, 9/15/80)
Member of the 1977 Secretary's Task Force on Compensation, NIH
- Dr. Lynn Carmichael (T, 4/3/82)
Chairman, Dept. of Family Medicine, Univ. of Miami School of Medicine
- Dr. John Caronna (C, *Defining Death, Foregoing Treatment*)
Prof. of Neurology, Cornell Univ. Medical College
- Dr. Eric J. Cassell (T, 1/10/81)
Physician; Clinical Professor of Public Health, Cornell Univ. Medical College

- Joan Cassell (T, 7/12/80)
Senior Research Assoc., Center for Policy Research, New York
- Dr. Ned Cassem (T, 6/4/81)
Chief of Psychiatric Liaison Service and Chairman,
Critical Care Committee, Mass. General Hospital, Boston
- Rosemary Chalk (C, *Whistleblowing*)
Program Head, Comm. on Scientific Freedom and
Responsibility, Amer. Assoc. for the Advancement of
Science
- Dr. Thomas Chalmers (T, 1/9/81)
President and Dean, Mt. Sinai School of Medicine of the
City Univ. of New York
- Dr. R. Chawla (P, 4/3/82)
Emory Univ. School of Medicine
- James F. Childress, Ph.D. (C, *Splicing Life*)
Prof. of Religious Studies, Univ. of Va.
- Dr. Barton Childs (T, 5/8/81)
Prof. of Pediatrics, Johns Hopkins Univ. School of
Medicine
- Thomas S. Chittenden (T, 9/15/80)
Senior Vice President, Marsh and McLennan, Inc.
- Dr. Marian Chivers (T, 4/2/82)
Medical Director, West End Medical Center, Atlanta, Ga.
- Dr. Sanford Chodish (C, IRB site visit)
Boston City Hospital, Mass.
- Dr. Shelly N. Chou, Ph.D. (C, *Defining Death*)
Chairman, Dept. of Neurosurgery, Univ. of Minn. Medical
School, Minneapolis
- Elsie Christianson (P, 9/11/81)
Testified about her difficulties with the VA hospital
where her husband was treated for Huntington's Disease
- Luther Christman (C, *Care Decisions*)
Dean, College of Nursing, Rush-Presbyterian-St. Luke's
Medical Center, Chicago
- Dr. W. Kemp Clark (C, *Defining Death*)
Physician, Dallas, Tx.
- Laura Clay (P, 8/13/82)
Representing Sen. Nickles of Okla.
- Charlotte B. Cloutier, M.A., M.P.A. (C, *Whistleblowing*)
Research Assoc., Medicine in the Public Interest
- Jeffrey M. Cohen, Ph.D. (C, IRB site visit)
State Univ. of N. Y., Albany
- Dr. Robert J. Cohen (C, *Foregoing Treatment*)
Asst. Prof. of Neurology, Va. Commonwealth Univ.,
Medical College of Virginia, School of Medicine
- John R. Connery, S.J. (C, *Splicing Life*)
Representing the U.S. Catholic Conference
- Dennis R. Connolly (T, 9/15/80)
Counsel to the Amer. Insurance Assoc., New York

Harris Coulter (P, 10/9/82)

Medical historian

Dr. Dale Cowan (C, IRB site visit)

St. Luke's Hospital, Cleveland, Oh.

William Crane (P, 6/4/81)

Director, Developmental Disabilities Law Center of
Mass.; Prof. of Law, Suffolk Univ. Law School

Dr. Ronald Cranford (C, *Defining Death, Foregoing
Treatment*; T, 7/11/80, 6/10/82) Assoc. Prof. of
Neurology, Univ. of Minn. Medical School, Minneapolis;
Director, Neurological Intensive Care Unit, Hennepin
County Medical Center, Minneapolis; Chairman, Ethics
Committee, Amer. Acad. of Neurology

Charles E. Curran, S.T.D. (C, *Splicing Life*)

Prof. of Moral Theology, Dept. of Theology, School of
Religious Studies, Catholic Univ.

Norman Daniels, Ph.D. (T, 3/13/81, 10/22/81)

Prof. of Philosophy, Tufts Univ.

Ann J. Davis (C, *Care Decisions*)

Prof., Univ. of Calif., San Francisco, School of Nursing

Carol Davis (P, 4/9/81)

Physical therapist

Karen Davis, Ph.D. (T, 3/14/81, 4/3/82)

Prof. of Health Services Admin., Johns Hopkins Univ.
School of Hygiene and Public Health

Peter Day, Ph.D. (C, *Splicing Life*)

Director, Plant Breeding Institute, Trumpington,
Cambridge, England

Philip Devine (T, 1/9/82)

Philosopher, Univ. of Scranton, Penn.

Lucile Dismukes, M.N. (T, 4/2/82)

Exec. Dir., Council on Maternal and Infant Health of the
State of Ga.

Rev. Charles W. Doak (T, 9/11/81)

IRB member, Univ. of Calif., Los Angeles, School of
Medicine

Dr. Avedis Donabedian (T, 3/13/81)

Nathan Sinai Distinguished Prof. of Public Health, Dept.
of Medical Care Organization, School of Public Health,
Univ. of Mich.

Sister Rosemary Donley (C, *Care Decisions*)

Dean, School of Nursing, Catholic Univ.

Dr. Raymond Duff (T, 1/9/82)

Pediatrician, Yale-New Haven Medical Center

Rhetaugh Graves Dumas (C, *Care Decisions*)

Deputy Director, National Institute of Mental Health

Andrew Duncan, M.H.A. (T, 2/12/82)

Asst. Admin., George Washington Univ. Hospital, Wash.,
D.C.

- Troy Duster, Ph.D. (C, *Splicing Life*)
Director, Institute for the Study of Social Change, Univ.
of Calif., Berkeley
- Gerald Dworkin, Ph.D. (T, 10/22/81)
Prof. of Philosophy, Univ. of Ill., Chicago Circle
- Allen R. Dyer (P, 5/17/80)
Testified on his own behalf
- Russell Dynes (T, 7/12/80)
Executive Officer, Amer. Sociological Assoc.
- Dr. Michael Earnest (C, *Defining Death, Foregoing Treatment*)
Dept. of Neurology, Denver General Hospital, Colo.
- Dr. Sol Edelstein (T, 12/12/81)
Director of the emergency room, George Washington
Univ. Hospital
- Dr. Albert Ehle (C, *Defining Death, Foregoing Treatment*)
Dept. of Neurology, Univ. of Tx., Southwestern Medical
School, Dallas
- Barbara and Michael England (T, 4/2/82)
Sprott, Ala. residents who testified about their
experience in obtaining and paying for prenatal and
delivery services
- Judge Patti Englander (T, 4/9/81)
State Attorney's office, Broward County, Fla. (Perlmutter
case)
- Dr. Richard W. Erbe (T, 5/8/81)
Medical Genetics Unit, Mass. General Hospital
- Veronica Evaneshko (C, *Care Decisions*)
Assoc. Prof., College of Nursing, Ariz. State Univ.
- Stephanie Ezrol (P, 6/11/82)
National Democratic Policy Comm.
- Dr. J.A. Fabro (P, 6/4/81)
Editor, *Connecticut Medicine*
- Ruth Faden, Ph.D., M.P.H. (T, 1/10/81)
Assoc. Prof. of Health Services Admin., Johns Hopkins
Univ. School of Hygiene and Public Health
- Dr. Olga Fairfax (P, 3/12/82, 6/10/82, 8/12/82)
Founder, United Methodists for Life
- Dr. Yomi Fakunle (C, *Foregoing Treatment*)
Chief Resident, Dept. of Neurology, George Washington
Univ. School of Medicine and Health Sciences
- Sister Margaret A. Farley (C, *Splicing Life*)
Assoc. Prof. of Ethics, Yale Divinity School
- Dr. James Farr (T, 4/10/81)
Pastor, Snyder Memorial United Methodist Church,
Jacksonville, Fla.
- Dr. Jack M. Fein (C, *Defining Death*)
Dept. of Neurological Surgery, Albert Einstein College of
Medicine, Yeshiva Univ.

Joel Feinberg, Ph.D. (T, 6/10/82)

Prof. of Philosophy, Univ. of Ariz.

Judge John G. Ferris (T, 4/9/81)

Trial judge of Broward County, Fla. (Perlmutter case)

Dr. Albert Fine (T, 6/4/81)

Director, Intensive Care Unit, Somerville Hospital, Mass.

Dr. Sal Fiscina, J.D. (C, *Defining Death*)

Physician, Chevy Chase, Md.

Jody Fleit (T, 6/5/81)

Former member of the oncology research unit at Boston Univ. Hospital

John G. Fleming, M.A., D. Phil., D.C.L. (T, 1/9/81)

Shannon Cecil Turner Prof. of Law, Univ. of Calif., Berkeley, School of Law (Boalt Hall)

Juanita W. Fleming (C, *Care Decisions*)

Prof. and Asst. Dean for Graduate Education, School of Nursing, Univ. of Ky.

Dr. Anne Fletcher (T, 1/9/82)

Director, Intensive Care Nursery, Children's Hospital, Wash., D.C.

John Fletcher, Ph.D. (C, *IRB Guidebook, Protecting Subjects, Splicing Life*; T, 1/9/82)

Asst. for Bioethics to the Director, Clinical Center, NIH

Gen Foley, M.S.N. (T, 6/4/81)

Asst. Director of Nursing, Memorial Sloan-Kettering Cancer Center, New York

Philippa Foot (T, 4/10/81)

Prof. of Philosophy, Univ. of Calif., Los Angeles; Senior Research Fellow, Somerville College, Oxford

Loretta C. Ford (C, *Care Decisions*)

Dean and Director of Nursing, Univ. of Rochester Medical Center

Dr. Spencer Foreman (C, *Whistleblowing*)

President, Sinai Hospital, Baltimore, Md.

Dr. Edwin Forman (T, 2/12/82)

Pediatric oncologist, R. I. Hospital, Providence

Irene Forsman, R.N., M.S. (C, *Screening and Counseling*)

Office of Maternal and Child Health, HHS

Dr. Norman Fost (C, IRB site visit; T, 5/8/81, 1/9/82)

Prof. of Pediatrics and of History of Medicine and Director, Medical Ethics Program, Univ. of Wisc. Medical School

Renée C. Fox, Ph.D. (C, *Compensation*)

Prof. of Sociology, Univ. of Penn.

Rabbi Samuel J. Fox (P, 6/4/81)

Testified on his own behalf

Dr. John Freeman (T, 1/9/82)

Pediatric neurologist, Johns Hopkins Hospital

- Charles Fried, J.D., (T, 10/22/81)
Prof. of Law, Harvard Univ. (statement submitted in lieu of an appearance)
- Dr. Terrance G. Furlow, J.D. (C, *Defining Death*)
Dept. of Legal Medicine, Armed Forces Institute of Pathology, Wash., D.C.
- Dr. J. Richard Gaintner (C, *Whistleblowing*)
Vice President and Deputy Director, Johns Hopkins Hospital; Assoc. Prof. of Medicine, Johns Hopkins Univ. School of Medicine
- Dr. Robert P. Gale (T, 9/11/81)
Dept. of Microbiology and Immunology, Univ. of Calif., Los Angeles
- Dr. David Garr (T, 4/3/82)
Co-Coordinator, Rural Practice Network, Inc., Denver, Colo.
- Dr. William Gartland (C, *Splicing Life*; T, 9/16/80)
Director, Office of Recombinant DNA Activities, NIH
- Dr. Schley Gatewood, Jr. (T, 4/2/82)
Physician, Americus, Ga.
- Clifton R. Gaus, M.H.A., Sc.D. (T, 11/13/81)
Director, Center for Health Policy Studies, Georgetown Univ.
- David Gauthier, Ph.D. (T, 10/22/81)
Prof. of Philosophy, Univ. of Pittsburgh
- Dr. Willard Gaylin (T, 6/10/82)
Psychoanalyst; President, Hastings Center, Hastings-on-Hudson, N.Y.
- Alan Gibbard, Ph.D. (T, 10/22/81)
Prof. of Philosophy, Univ. of Mich.
- Leonard H. Glantz, J.D. (C, *Compensation, Whistleblowing*; T, 6/4-5/81)
Boston Univ. Schools of Medicine and Public Health; IRB member at Boston Univ. Medical Center
- Dr. Robert Goldenberg (T, 4/2/82)
Assoc. Prof. of Obstetrics/Gynecology, Univ. of Ala. School of Medicine
- Dr. Eli Goldensohn (C, *Defining Death*)
Neurological Institute, New York
- Andrew Good, J.D. (T, 6/5/81)
Attorney for Dr. Marc Straus
- Dr. Robert Gordon, M.H.S. (T, 3/14/81)
Special Asst. to the Director, NIH
- Sam Gorovitz (P, 9/10/82)
Prof. of Philosophy, Univ. of Md.
- Susan R. Gortner (C, *Care Decisions*)
Prof. and Assoc. Dean for Research, Univ. of Calif., San Francisco, School of Nursing

- Dr. Jack Grabow (C, *Defining Death*)
Mayo Clinic, Rochester, Minn.
- Frank P. Grad, LL.B. (C, *Whistleblowing*)
Joseph P. Chamberlain Prof. of Legislation and Director,
Legislative Drafting Research Fund, Columbia Law
School
- Dr. Frederick C. Green (C, IRB site visit; T, 9/11/82)
Assoc. Director, Children's Hospital, Wash., D.C.; IRB
Chairman
- Lawrence W. Green, Ph.D. (12/11/81)
Schools of Government and Public Health, Harvard
Univ.
- Dr. Phillip M. Green (C, *Defining Death*)
Dept. of Neurology, Marshfield Clinic, Wisc.
- Bernard H. Greene, LL.B. (T, 2/12/82)
Visiting Lecturer, Yale Law School; partner, Paul, Weiss,
Rifkind, Wharton and Garrison, New York
- Dr. Ake Grenvik (C, *Defining Death*)
Medical Director, Intensive Care Unit and Prof. of
Anesthesiology and Surgery, Univ. of Pittsburgh School
of Medicine
- Thomas Grisso, Ph.D. (T, 2/12/82)
Prof. of Psychology, St. Louis Univ.
- Jeanne Guillemin (T, 1/9/82)
Sociologist, Boston College
- James M. Gustafson (C, *Splicing Life*; T, 10/23/81)
Prof. of Theological Ethics, Univ. of Chicago
- Amy Gutmann, Ph.D. (T, 3/13/81)
Asst. Prof. of Politics, Princeton Univ.
- Dr. David Hamburg (T, 1/14/80)
President, Institute of Medicine; Vice Chairman, DHEW
Ethics Advisory Board
- Joel Handler, J.D. (T, 10/22/81)
Prof. of Law, Georgetown Univ.
- Stephanie Hall (P, 10/22/81)
Student, Univ. of Md., Baltimore
- Dr. Paul Hardy (T, 6/4/81)
Neuropsychiatrist, Paul Dever State School, Taunton,
Mass.; Asst. Prof. of Neurology, Tufts Univ.
- Daisy Harris (T, 4/2/82)
Executive Director, West End Medical Center, Atlanta
- Zsolt Harsanyi, Ph.D. (C, *Splicing Life*)
Office of Technology Assessment
- Dr. Mary Harvey (T, 1/9/81)
Robert Wood Johnson Clinical Scholar, Yale Univ.
- Dr. Frances Healy (T, 9/12/81)
Physician, Burlingame, Calif.; Chairwoman, Comm. on
Evolving Trends, Calif. Medical Assoc.

Erica Heath (C, IRB site visit)

Univ. of Calif., San Francisco, School of Medicine

Audrey Heimler, M.S. (T, 3/12/82)

Genetic Counselor, Long Island Jewish-Hillside Medical Center, New York

Dr. Dorothy Henneman (P, 6/4/81, 2/12/82, 10/9/82)

Physician and Prof. of Medicine; involved with admissions committees at three medical schools

Charles E. Henry, Ph.D. (C, *Defining Death*)

Dept. of Neurology, Va. Commonwealth Univ., Medical College of Va., School of Medicine

Dr. Eugene Hildreth (T, 4/3/82)

Chairman, Board of Internal Medicine and Chief of Medicine, Reading Hospital, Penn.

Dr. Kurt Hirschhorn (T, 3/12/82)

Prof. and Chairman, Dept. of Pediatrics, Mt. Sinai School of Medicine of the City Univ. of New York

John C. Hoffman (P, 5/17/80)

Representing Bell of Atri

David Hoines, J.D. (T, 4/9/81)

Attorney for Abe Perlmutter

Dr. John Holloman, Jr. (T, 3/13/81)

Regional Medical Officer, Region III, Food and Drug Admin.

Edward Holmes (T, 9/15/80)

Assoc. Prof. of Medicine, Duke Univ. School of Medicine; representing the Assoc. of Amer. Medical Colleges

Dr. Neal A. Holtzman (T, 3/12/82)

Coordinator, Hereditary Disorder Services, Preventive Medicine Admin., Md. Dept. of Health and Mental Hygiene; Assoc. Prof. of Pediatrics, Johns Hopkins Univ. School of Medicine

Thomas Horkan, J.D. (T, 4/10/81)

Attorney; representing the Florida Catholic Conference

Harold W. Horowitz, S.J.D. (T, 9/11/81)

Vice Chancellor of Faculty Relations, Univ. of Calif., Los Angeles

Elaine Hubbard, R.N., E.D.D. (T, 4/3/82)

Assoc. Prof., Univ. of Rochester School of Nursing

Ruth Hubbard, Ph.D. (C, *Splicing Life*)

Harvard Biological Laboratories, Harvard Univ.

Dr. John R. Hughes, Ph.D., DM (C, *Defining Death*)

Prof. of Neurology, Univ. of Ill. College of Medicine

Richard Hull, Ph.D. (T, 9/16/80)

Assoc. Prof. of Philosophy, State Univ. of N. Y., Buffalo

Peter Barton Hutt, Esq. (C, *Splicing Life*)

Attorney, Covington & Burling, Wash., D.C.

Sharon Imbus, R.N., M.Sc. (T, 9/12/81)

Burn Center, Univ. of Southern Calif. School of Medicine

Dr. Joseph K. Indenbaum (T, 9/12/81)

Medical Director, Los Angeles County Dept. of Health Services

Dr. David Jackson (C, *Splicing Life*)

Vice President and Chief Scientific Officer, Genex Corporation, Rockville, Md.

Stanley B. Jones (T, 5/16/80)

Fullerton, Jones and Wolkstein, Health Policy Alternatives, Inc., Silver Spring, Md.

Dr. Michael Kaback (T, 5/8/81)

Prof. of Pediatrics and of Medicine, Univ. of Calif., Los Angeles, School of Medicine

Norman Kahn, Ph.D. (C, IRB site visit)

Columbia Univ. School of Physicians and Surgeons

Dr. Robert Kaiser, (T, 9/12/81)

Co-chairman, Joint Los Angeles County Bar Medical Assoc. ad hoc Comm. on Biomedical Ethics

Dr. Yuet Wai Kan (C, *Splicing Life*)

Univ. of Calif., San Francisco, School of Medicine

Dr. Leon Kass (C, *Splicing Life*)

Henry R. Luce Prof. of the Liberal Arts of Human Biology, Univ. of Chicago

Barbara Katz (T, 1/9/81)

Counsel, Univ. of Mass. Medical Center

Dr. Howard Kaufman (C, *Defining Death*)

Univ of Tx. Medical School, Houston

Caroline Kaufmann, Ph.D. (C, *Care Decisions*)

Asst. Prof., Dept. of Sociology, Univ. of South Fla., Tampa

David Kefauver (T, 7/12/80)

Assoc. Admin. for Extramural Programs, Alcohol, Drug Abuse, and Mental Health Admin., HHS

Miriam Kelty, Ph.D. (C, *IRB Guidebook*)

Behavioral and Neural Sciences Review Section, NIH

Carol Kennon (T, 1/9/82)

Social worker, Intensive Care Nursery, Children's Hospital, Wash., D.C.

Patricia King (T, 7/10/82)

Member, Recombinant DNA Advisory Comm., NIH; Prof. of Law, Georgetown Univ. (statement submitted in lieu of an appearance)

Dr. Robert B. King (C, *Defining Death*)

Chairman, Dept. of Neurosurgery, State Univ. of N. Y., Upstate Medical Center, College of Medicine, Syracuse

Ronald Kokinda (P, 10/9/82)

Representing the National Democratic Policy Comm.

- Gretchen Kolsrud, Ph.D. (C, *Splicing Life*) Program Manager, Genetics and Population Program, Office of Technology Assessment
- Dr. Anthony Komaroff (T, 11/13/81)
Brigham and Women's Hospital, Boston
- Gerald P. Koocher, Ph.D. (T, 2/12/82)
Acting Chief Psychologist, Children's Hospital Medical Center, Boston
- Dr. Julius Korein (C, *Defining Death*; T, 7/11/80)
Prof. of Neurology, N. Y. Univ. Medical Center
- Sheldon Krinsky, Ph.D. (C, *Splicing Life*)
Dept. of Urban and Environmental Policy, Tufts Univ.
- Irving Ladimer (T, 9/15/80)
Program Director, Amer. Arbitration Assoc.
- Michael Lambert (T, 9/16/80)
Professional Asst., Technology Assessment and Risk Analysis, National Science Foundation
- Dr. Thomas W. Langfitt (C, *Defining Death*)
Dept. of Neurology, Hospital of the Univ. of Penn., Philadelphia
- Patricia Lanham (T, 4/2/82)
Kennesaw, Ga. resident who testified about her experience in obtaining and paying for prenatal and delivery services
- Martha Weinman Lear (T, 7/10/81)
Author of *Heartsounds*
- Karen Lebacqz, Ph.D. (C, *Splicing Life*)
Assoc. Prof. of Christian Ethics, Pacific School of Religion, Berkeley, Calif.
- Dr. Robert I. Lehrer (T, 9/11/81)
Prof. of Medicine, Univ. of Calif., Los Angeles, School of Medicine; Human Subject Protection Comm. (IRB) member
- Dr. Claire O. Leonard (T, 5/8/81)
Asst. Prof. of Pediatrics and of Obstetrics/Gynecology, Johns Hopkins Univ. School of Medicine
- Anngel Leply (T, 4/2/82)
Nashville, Tenn. resident who testified about her experience in paying for health care for her children
- Dr. Richard J. Lesco, J.D. (P, 9/12/81)
Physician; Torrance, Calif.
- Dr. Jerry Lewis (T, 1/9/81)
Prof. of Medicine and of Pathology, Chief of the Section of Hematology and Oncology, Univ. of Calif., Davis, School of Medicine; representing the Assoc. of Amer. Cancer Institutes

Dr. Robert J. Levine (C, *Protecting Subjects, Splicing Life, Whistleblowing*; T, 1/9/80, 9/11/82)

Prof. of Medicine and of Pharmacology, Yale Univ.

School of Medicine; IRB Chairman

Dr. Norman G. Levinsky (T, 6/5/81)

Physician-in-Chief, Boston Univ. Hospital; representing the Boston Univ. Medical Center administration

Dr. David Levy (T, 12/12/81)

Cornell Univ. Medical Center, New York

Charles Lidz, Ph.D. (T, 1/10/81)

Assoc. Prof. of Psychiatry and of Sociology, Western Psychiatric Institute and Clinic, Pittsburgh

Dr. Warren Lindau (T, 4/9/81)

Cardiologist; President, Dade County Medical Society, Fla.

Dr. James J. Lipsky (C, *IRB Site Visit*; T, 9/11/82)

Asst. Prof. of Medicine, Johns Hopkins Univ. School of Medicine; IRB member

Steve Lipton, Esq. (T, 9/12/81)

Attorney, Musick, Peeler, & Garrett, Los Angeles;

Legislative Asst. to Assemblyman Barry Keene at the time the Natural Death Act was passed

Dr. James LoGerfo, M.P.H. (T, 3/13/81)

Assoc. Prof. of Medicine and of Health Services, Univ. of Wash.

Dr. Cesare T. Lombroso (C, *Defining Death*)

Seizure Unit, Children's Hospital Medical Center, Boston

Ruth Watson Lubic, Ph.D. (C, *Care Decisions*; T, 12/11/81)

General Director, Maternity Center Assoc., New York

Roy Lubove (C, *Compensation*)

School of Social Work, Univ. of Pittsburgh

Jeanne Luckett (T, 4/2/82)

Chairwoman, Miss. Coalition for Mothers and Babies

Harold Luft, Ph.D. (T, 11/13/81)

Prof., Health Policy Program, Univ. of Calif., San Francisco

Dr. Audrey Manley (T, 3/12/82)

Director, Genetic Services Programs, Office of Maternal and Child Health, HHS

Dr. Peter Mansell (T, 4/9/81)

Assoc. Prof. of Medical Oncology, Univ. of Miami Comprehensive Cancer Center

Jerry L. Mashaw, LL.B., Ph.D. (C, *Whistleblowing*; T, 9/11/81)

Prof. of Law, Yale Law School

Dr. Richard L. Masland (C, *Defining Death*)

Neurological Institute, New York

Jackie Matuseski (P, 4/9/81)

Social worker and administrator of a hospice program

Diana J. McCann (T, 9/15/80)

Director, Human Subjects Office, Univ. of Wash.

Charles R. McCarthy, Ph.D. (C, *IRB Guidebook*,
Whistleblowing)

Director, Office for Protection from Research Risks, NIH

Rev. Donald G. McCarthy, Ph.D. (C, *Splicing Life*)

Director of Education, Pope John XXIII Medical-Moral
Research and Education Center, St. Louis, Mo.

Father Richard McCormick (T, 6/10/82)

Kennedy Institute, Georgetown Univ.

Rev. Timothy McDonald (T, 4/2/82)

Asst. Pastor, Ebenezer Baptist Church, Atlanta, Ga.
testified about experiences of his congregants in
obtaining and paying for health care

Dr. James F. McDonough (T, 6/5/81)

Chairman, Mass. Board of Registration and Discipline in
Medicine

Joan McDowell (C, Privacy)

Program in Medicine, Law, and Human Values, Univ. of
Calif., Los Angeles

Dr. Nelson McGhee (T, 4/2/82)

Physician, Atlanta, Ga.

Vynette McGlawn (T, 4/9/81)

Administrator, Jackson Heights Nursing Home, Miami

Dr. Kevin M. McIntyre, J.D. (C, *Defining Death*; T, 6/4/81)

Cardiologist, West Roxbury V.A. Hospital, Mass.;
Chairman, National Comm. on Emergency Cardiac Care,
Amer. Heart Assoc.

Rev. Donald McKinney (T, 4/10/81)

Board member and founder of Concern for Dying

Gloria McNally (P, 10/8/82)

Social worker; completed a 10-year retrospective study
(under the direction of Dr. Claire Leonard) of parents
and genetic counseling with Johns Hopkins Univ.

Alan Meisel, J.D. (T, 1/10/81)

Assoc. Prof. of Law and Psychiatry, Univ. of Pittsburgh

Dr. Sherman M. Mellinkoff (T, 9/11/81)

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Richard Mellman (T, 11/13/81)

Vice President and Actuary, The Prudential Insurance
Co.

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National Institute on Aging

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Technology Assessment and Risk Analysis Group,
Division of Policy Research and Analysis, National
Science Foundation

Bruce Miller, Ph.D. (T, 9/12/81)

Philosopher, East Lansing, Mich.; worked on the
proposed Michigan Medical Treatment Decision Act

Dr. Don Harper Mills (C, *Defining Death*)

Physician, Long Beach, Calif.

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Prof. and Chairman, Dept. of Neurology, George Washington Univ. School of Medicine and Health Sciences

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Former member of the oncology research unit, Boston Univ. Hospital

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Director, Division of Biomedical Research, AAMC

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Hospital chaplain and founder of the Methodist Hospice, Jacksonville, Fla.

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Dr. Robert F. Murray, Jr. (T, 5/8/81)

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Attorney; handled the state appeal in the Perlmutter case

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Former patient at Boston Univ. Hospital

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Oncology Unit, Univ. of Miami Hospital

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Director of Policy, Planning and Publication, Candlelighters Foundation, Wash., D.C.; mother of a young boy who died of leukemia

J. Robert Nelson, Ph.D. (C, *Splicing Life*; P, 7/10/82)

Prof. of Theology and Ethics, Boston Univ.; representing the National Council of Churches

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Representing the Assoc. for the Severely Handicapped

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Science Foundation
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- Dr. Mark Novitch (T, 5/16/80)
Acting Deputy Commissioner, Food and Drug Admin.
- Andra N. Oakes, J.D. (C, *Whistleblowing*)
Partner, Dobrovir, Oakes and Gebhardt, Wash., D.C.
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Montgomery County Right to Life, Md.
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Admin. Officer for Social and Ethical Responsibility,
Amer. Psychological Assoc.
- Christine Oliver, Ph.D. (C, *Splicing Life*)
Oil, Chemical and Atomic Workers International Union,
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Assoc. Director for Human Resources, Veterans, and
Labor, Office of Management and Budget, Executive
Office of the President
- Rev. Kevin O'Rourke, O.P., J.C.D., S.T.L. (C, *Splicing Life*;
T, 7/11/80)
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Admin., Regional Memorial Hospital, Brunswick, Me.;
representing the Amer. Hospital Assoc.
- John Paris, S.J. (P, 6/10/82)
Theologian, Holy Cross College and Univ. of Mass.
Medical School
- Dr. Alvin E. Parrish (C, *IRB Guidebook*, IRB site visit; T,
9/11/82)
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Medicine and Health Sciences; IRB Chairman
- Dr. Edmund Pellegrino (T, 7/10/81)
President, Catholic Univ.

J.W. Peltason (T, 7/12/80)

President, Amer. Council on Education

Beverly Penrose (C, IRB site visit)

St. Louis Univ. Medical Center

Martin Pernick, Ph.D. (T, 7/10/81)

Asst. Prof. of History of Medicine, Dept. of History,
Univ. of Mich.

Dr. Joseph Perpich (T, 9/16/80)

Exec. Secretary, Federal Interagency Advisory Comm. on
Recombinant DNA Research, NIH

Dr. Seymour Perry (T, 1/9/81)

Former Head, Secretary's Task Force on the
Compensation of Injured Research Subjects (statement
submitted in lieu of an appearance)

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Johns Hopkins School of Hygiene and Public Health

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Protection Study Comm.

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- Dr. Walter Sackett (P, 4/9/81)
Pediatrician; former Fla. State Representative; introduced
the nation's first "death with dignity" bill
- Dr. Robert M. Sade (T, 10/22/81)
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- Barbara T. Syska (P, 8/13/82)
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- Rabbi Moses Tendler (T, 7/11/80)
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Attorney, Public Citizen Litigation Group, Wash., D.C.

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Editorial Board, *New York Times*; author of *The Ultimate Experiment: Man-Made Evolution*

Dr. Earl Walker (C, *Defining Death*; T, 7/11/80)

Adjunct Prof. of Neurosurgery and of Neurology, Univ. of N. M. School of Medicine

Wanda Walker (T, 4/2/82)

Clinton, Miss. resident who testified about her experience in obtaining and paying for health care for her children

George Wallace-Barnhill (P, 4/9/81)

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Director, Catholic Charities, Archdiocese of Miami, Fla.

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Participation in Biomedical Research
(Pharmaceutical Manufacturers Association)

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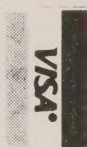
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